Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration (NUREG-1556, Vol. 3)

Publication Information

Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration

Final Report

NRC Report Number: NUREG-1556, Vol. 3

Availability Notice

Manuscript Completed: July 1998

Date Published: July 1998

J. Lubinski, S. Baggett, D. Broaddus, M. Burgess, E. Compton, K. Randall, T. Rich, B. Smith

Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Abstract

As part of its redesign of the materials licensing process, the United States Nuclear Regulatory Commission (NRC) is consolidating and updating numerous guidance documents into a single comprehensive repository, as described in NUREG-1539, "Methodology and Findings of the NRC's Materials Licensing Process Redesign," and draft NUREG-1541, "Process and Design for Consolidating and Updating Materials Licensing Guidance." NUREG-1556, Vol. 3, "Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration," dated July 1998, is designed to provide applicants for requests for a sealed source or device safety evaluations. It also provides reviewers of such requests with the information and materials necessary to determine that the products are acceptable for licensing purposes. It provides the applicants and reviewers with information concerning how to file a request, a listing of the applicable regulations and industry standards, policies affecting

evaluation and registration, certain administrative procedures to be followed, information on how to perform the evaluation and write a registration certificate, and the responsibilities of the registration certificate holder.

This document combines and supersedes the guidance previously found in NUREG-1550, "Standard Review Plan for Applications for Sealed Source and Device Evaluations and Registrations," Regulatory Guide 10.10, "Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Devices Containing Byproduct Material," Regulatory Guide 10.11, "Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Sealed Sources Containing Byproduct Material," and the Office of Nuclear Material Safety and Safeguards Policy and Guidance Directives 84-22, "What Source and Device Designs Require an Evaluation," and 84-5, "Source and Device Evaluation Technical Assistance Request."

This report incorporates suggestions submitted during the comment period on draft NUREG-1556, Vol. 3. When published, this final report should be used in preparing sealed source and device applications. NRC staff will use this final report in reviewing these applications.

Foreword

The NRC is using Business Process Redesign techniques to redesign its materials licensing process. This effort is described in NUREG-1539. A critical element of the new process is consolidating and updating numerous guidance documents into a NUREG-series of reports. Below is a listing of volumes currently included in the NUREG-1556 series:

Vol. No.	Volume Title	Status
1	Program-Specific Guidance About Portable Gauge Licenses	Final Report
2	Program-Specific Guidance About Radiography Licenses	Final Report
3	Applications for Sealed Source and Device Evaluation and Registration	Final Report
4	Program-Specific Guidance About Fixed Gauge Licenses	Draft for Comment
5	Program-Specific Guidance About Self-Shielded Irradiator Licenses	Draft for Comment
6	Program-Specific Guidance About 10 CFR Part 36 Irradiator Licenses	Draft for Comment

NUREG-1556, Vol. 3, "Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration," dated July 1998, provides applicants requesting a sealed source or device safety evaluation, and reviewers of such requests, with the information and materials necessary to make determinations that the products are acceptable for licensing purposes. It provides the applicants and reviewers with information concerning how to file a request, a listing of the applicable regulations and industry standards, policies affecting evaluation and registration, certain administrative procedures to be followed, information on how to perform the evaluation and write a registration certificate, and the responsibilities of the registration certificate holder.

A team composed of NRC headquarters staff prepared NUREG-1556, Vol. 3, drawing on its collective experience in radiation safety in general and as specifically applied to sealed source and devices designs, and the experience gained through development and publication of NUREG-1550, "Standard Review Plan for Applications for Sealed Source and Device Evaluations and Registrations," that was published in 1996.

NUREG-1556, Vol. 3, represents a step in the transition from the current paper-based process to the new electronic process. This document is available on the Internet at the following address: <http://www.nrc.gov/NRC/NUREG/SR1556/V3/index.html>.

This report describes and makes available to the public information on: methods acceptable to the NRC staff for implementing specific parts of the Commission's regulations; techniques the staff uses in evaluating applications, including specific problems or postulated accidents; and data the NRC staff needs to review applications for source and device registration. NUREG-1556, Vol. 3, is not a substitute for NRC regulations, and compliance is not required. The approaches and methods described in this report are provided for information only. Methods and solutions different than those described in this report will be acceptable, if they provide enough information for the staff to make the determinations needed to issue, continue, or reject a license.

Frederick C. Combs, Acting Director
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards

Figures

4.2a Smoke and Chemical Agent Detectors. *Smoke and chemical agent detectors are products distributed to persons exempt from licensing under 10 CFR 30.20.*

4.2b Smoke and Chemical Agent Detectors. *Smoke and chemical agent detectors are products distributed to persons exempt from licensing under 10 CFR 30.20.*

4.3a 10 CFR 31.5 General License. *Gas chromatographs devices are products used under 10 CFR 31.5 general license.*

4.3b 10 CFR 31.5 General License. *Density gauge devices are products used under 10 CFR 31.5 general license.*

4.3c 10 CFR 31.5 General License. *Static elimination devices are products used under 10 CFR 31.5 general license.*

4.4a 10 CFR 31.7 General License. *Safety devices, such as exit signs, containing tritium or promethium-147 and used in aircraft may be used under 10 CFR 31.7 general license.*

4.4b 10 CFR 31.7 General License. *Safety devices, such as exit signs, containing tritium or promethium-147 and used in aircraft may be used under 10 CFR 31.7 general license.*

4.5 Radiography Equipment. *Radiography equipment, such as the equipment shown above, must meet the requirements of 10 CFR Part 34.*

4.6 Well-Logging Operations. *Sealed sources used in well-logging operations must meet the requirements of 10 CFR Part 39.*

4.7a Irradiators. *NRC evaluates (a) category I (self-shielded) irradiators used in category IV (Panoramic, wet source storage) irradiators.*

4.7b Irradiators. *NRC evaluates (b) sealed sources used in category IV (Panoramic, wet source storage) irradiators.*

5.1 Calibration and Reference Sources. *Calibration and reference sources may not need evaluation and registration by IMNS.*

5.2 Map of the World. *Foreign vendors are required to establish an address in the United States to which the NRC can correspond and serve papers as necessary to accomplish its mission.*

5.3 Computer Software. *Safety evaluations concentrate only on those systems that control fundamental safety processes such as checking an interlock, source or shielding position, and the functionality of position indicators.*

5.4 Packaging and Transportation. *Registration certificate holders must meet all NRC and DOT*

requirements for packaging and transporting sealed sources and devices.

10.1 Radiation Profiles. *ANSI-538 suggests radiation profiles be provided as indicated above.*

10.2 Installation and Servicing of Devices. *Applicants must specify the qualifications needed by individuals to perform installation and servicing of devices.*

Acknowledgments

The writing team thanks the individuals listed below for assisting in the development and review of the report. All participants provided valuable insights, observations, and recommendations.

The team also thanks Traci S. Kime and Mary Louise Roe of NRC, Angela S. Case of Total Systems Solutions, Inc., and Judy Boykin, Tina Jordan, D. W. Benedict Llewellyn, Alyce Martin, Steve Schawaroch, and Gina Thompson of Computer Sciences Corporation.

The Participants

Baggett, Steven L.
Broaddus, Douglas A.
Burgess, Michele L.
Camper, Larry W.
Compton, Eric B.
Cool, Donald A.
Jankovich, John P.
Lee, Sueng J.
Lubinski, John W.
Randall, KimBerly B.
Rich, Thomas W.
Schwartz, Maria E.
Smith, Brian W.
Vacca, Patricia C.

Abbreviations

ALARA	As Low As is Reasonably Achievable
ANSI	American National Standards Institute
CFR	Code of Federal Regulations
DCD	Document Control Desk
FDA	United States Food and Drug Administration
GPO	Government Printing Office
IMNS	Division of Industrial and Medical Nuclear Safety
ISO	International Organization of Standardization
MOU	Memorandum of Understanding
NARM	Naturally occurring or Accelerator-produced Radioactive Material
NRC	United States Nuclear Regulatory Commission
OCO	Office of the Controller
OGC	Office of the General Counsel
OSP	Office of State Programs
QA	Quality Assurance
QC	Quality Control

1 Purpose of Draft Report

This NUREG provides assistance to applicants on submitting requests to the NRC for radiation safety evaluation and registration of sealed sources and devices containing byproduct material. In addition, it is designed to provide the reviewer of such requests for sealed source and device safety evaluations with guidance, information, and materials necessary to make a determination that the product is acceptable for licensing purposes. It provides the applicants and reviewers with information concerning how to file a request, a listing of the applicable regulations and industry standards, policies affecting evaluation and registration, certain administrative procedures to be followed, information on how to perform the evaluation and write a registration certificate, and the responsibilities of the registration certificate holder.

Radiation safety programs for the use of byproduct material as a sealed source or device are structured on the presumption that the byproduct material will not breach its containment and contaminate the environment or unnecessarily expose individuals to radiation. This presumption depends largely upon the adequacy of the containment properties of the sealed sources or devices in withstanding the stresses imposed by the environment in which they are possessed and used.

The regulations provided in Title 10 of the Code of Federal Regulations (CFR), Section 30.32(g), require an applicant for a specific license to use a sealed source or device to identify the sealed source or device as registered with NRC in accordance with 10 CFR 32.210 or to provide the information contained in 10 CFR 32.210. 10 CFR 32.210 provides for the registration of a product and provides a means for having a single safety evaluation of the product performed. This process allows applicants and license reviewers to reference the evaluation when licensing the product for use or distribution without having to perform a complete evaluation of the product for each licensing action.

The NRC maintains a registry of radiation safety information on sealed sources and devices containing byproduct material. Agreement States also provide information on their radiation safety evaluations to the NRC for the registry. Both the NRC and the Agreement States use the information in the registry. Thus a vendor needs to provide detailed information about its sealed source or device only to a single agency, and the results of the radiation safety evaluation will be available for use in granting licensing approval to users of the device throughout the United States.

Any information collection activities mentioned in this document are contained as requirements in 10 CFR Parts 19, 20, 21, 30, 31, 32, 34, 35, 36, 39, 40, 70, and 71, which provide the regulatory basis for this document. The information collection requirements in these parts have been cleared under Office of Management and Budget Clearance Nos. 3150-0044, 3150-0014, 3150-0035, 3150-0017, 3150-0016, 3150-0001, 3150-0007, 3150-0010, 3150-0158, 3150-0130, 3150-0020, 3150-0009, and 3150-0008, respectively.

2 Agreement States

Certain states, called Agreement States (see Figure 2.1), have entered into agreements with the NRC that give them the authority for certain activities, including performing safety evaluations and registration of byproduct, source, or special nuclear materials used, possessed, or distributed by persons within their borders. A current list of Agreement States (including names, addresses, and telephone numbers of responsible officials) may be obtained upon request from the NRC's Office of State Programs (OSP). Any applicant, other than a Federal agency or distributor of a product to persons exempt from licensing, that is located in an Agreement State and wishes to apply for safety evaluation and registration of a sealed source or device needs to contact the responsible officials in that State for guidance on preparing an application; file these applications with State officials, not with the NRC. Table 2.1 provides a quick way to check on which agency has regulatory authority.

Six Agreement States (Iowa, Nevada, New Mexico, North Dakota, Oregon, and Utah) have voluntarily relinquished their authority to perform sealed source and device safety evaluations. Applicants and registration certificate holders located in these States are regulated by the NRC in the same manner, with respect to sealed source and device registration, as those not located in an Agreement State.

When an Agreement State issues a registration certificate, a copy of the registration certificate is forwarded to the Division of Industrial and Medical Nuclear Safety (IMNS) by the State. IMNS performs an administrative review of each certificate that includes looking for gross errors or omissions and ensures the inclusion of all necessary information on the first page of the certificate. The certificate is incorporated into the national registry, and copies are distributed to the NRC regions, all Agreement States, and appropriate Federal and international agencies. If any administrative problems or errors are identified with an Agreement State registration certificate, they are resolved directly with the Agreement State.

Agreement State regulations may vary from NRC regulations. As such, sealed sources or devices registered by an Agreement State may not have met the regulations required of an NRC licensee. In addition, the NRC may identify significant safety concerns about a sealed source or device that has been evaluated by an Agreement State. In these cases, IMNS will continue to incorporate the registration certificate into the national registry. However, a cover letter indicating why the sealed source or device is not approved for use by NRC licensees is attached to the registration certificate. IMNS will raise the safety issues with the State that issued the registration certificate and with the vendor through OSP. In addition, the NRC will attempt to obtain a listing of any NRC licensees that may have acquired the device and will take appropriate action. Corrective actions to resolve the registration issues, if any, will be the responsibility of the Agreement State.

The above process is necessary to: (1) ensure that NRC license reviewers are aware of particular NRC concerns with the registration certificate and (2) provide other Agreement States with the information necessary to determine whether a license to use the sealed source or device should be approved. If the registration certificates and cover letters are not included, an NRC or Agreement State license reviewer may receive a copy of the registration certificate directly from the

registration certificate holder or an Agreement State and may inadvertently assume that products listed in the registration certificate are acceptable for licensing.

Table 2.1 Who Evaluates Sealed Sources and Devices?

Applicant and its Location	Regulatory Agency
Distributor of products to persons exempt from licensing regardless of location	NRC
Federal agency regardless of location	NRC
Non-Federal entity in non-Agreement State, US territory or possession	NRC
Non-Federal entity in Agreement State at non-Federally controlled site	Agreement State
Non-Federal entity in Agreement State at Federally-controlled site NOT subject to exclusive Federal jurisdiction	Agreement State
Non-Federal entity in Agreement State at Federally-controlled site subject to exclusive Federal jurisdiction	NRC

Figure 2.1 U.S. Map. *Location of NRC Offices and Agreement States. As of October 1, 1998, the Walnut Creek Field Office will close. All communications should be forwarded to Region IV.*

3 Management Responsibility

The NRC recognizes that effective applicant/registration certificate holder management is vital to achieving safety and complying with regulatory requirements. The NRC also believes that consistent compliance with its regulations provides reasonable assurance that regulated activities will be conducted accordingly. Based on results of routine and special inspections of licensed activities, the NRC has determined that ineffective management is frequently the underlying cause of compliance problems. Management refers to a senior-level manager who has responsibility for overseeing regulated activities.

To ensure adequate management involvement, a management representative must sign the submitted application acknowledging management's commitments and responsibility for the following:

- Completeness and accuracy of records and all information provided to the NRC (10 CFR 30.9);
- Knowledge about the contents of the application;
- Applying for a registration certificate amendment if the information provided in the

application or contained in the certificate is modified or changed. Registration certificate holders must comply with the information in the registration certificate until the certificate is amended; and,

- Committing adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to ensure that the registration certificate holder meets its regulatory requirements. The registration certificate holder is required to manufacture or distribute the product in accordance with:

  - the statements and representations contained in the application for safety review and registration;

  - the provisions of the registration certificate; and,

  - NRC regulations.

Applicants and registration certificate holders may be subject to enforcement actions due to noncompliance with regulatory requirements. For information on the NRC enforcement program, see "General Statement of Policy and Procedures for NRC Enforcement Actions," (NUREG-1600), which is available from the NRC upon request. NUREG-1600 is also available on the Internet. Visit NRC's Home Page < http://www.nrc.gov >, choose "Nuclear Materials," then "Enforcement Program," "Enforcement Guidance Documents," and then "Enforcement Policy."

4 Applicable Regulations

It is the applicant's or registration certificate holder's responsibility to have up-to-date copies of applicable regulations, read them, and abide by each applicable regulation.

The following Parts of 10 CFR Chapter I contain regulations applicable to sealed source and device evaluations:

- 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders"
- 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigation"
- 10 CFR Part 20, "Standards for Protection against Radiation"
- 10 CFR Part 21, "Reporting of Defects and Noncompliance"
- 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material"
- 10 CFR Part 31, "General Domestic Licenses for Byproduct Material"
- 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material"
- 10 CFR Part 34, "Licenses for Radiography and Radiation Safety Requirements for Radiographic Operations"
- 10 CFR Part 35, "Medical Use of Byproduct Material"
- 10 CFR Part 36, "Licenses and Radiation Safety Requirements for Irradiators"
- 10 CFR Part 39, "Licenses and Radiation Safety Requirements for Well Logging"
- 10 CFR Part 40, "Domestic Licensing of Source Material"

- 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material”

- 10 CFR Part 71, “Packaging and Transportation of Radioactive Material”

- 10 CFR Part 170, “Fees for Facilities, Materials, Import and Export Licenses and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended”

- 10 CFR Part 171, “Annual Fees for Reactor Operating Licenses, and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by NRC”

To request copies of the above documents, call the Government Printing Office (GPO) order desk in Washington, DC at (202) 512-1800. Order the two-volume bound version of Title 10, CFR, Parts 0-50 and 51-199 from the GPO, Superintendent of Documents, Post Office Box 371954, Pittsburgh, Pennsylvania 15250-7954. Single copies of the above documents may be requested from the NRC's Regional or Field Offices (see Figure 2.1 for addresses and telephone numbers).

The regulations embodied in 10 CFR 30.32(g) and 32.210 codify the current and long-standing practice whereby vendors of sealed sources of radioactive material and devices containing sealed sources submit radiation safety information necessary to perform an independent, technical safety evaluation, and to obtain registration of radiation safety information on certain sealed sources and devices. The practice has been used by the United States Atomic Energy Agency/NRC since the 1950's and by the Agreement States starting in 1962.

The specific provisions in 10 CFR 30.32(g) require a license applicant to either make reference to a registered sealed source or device or provide the information necessary to perform a safety evaluation of the sealed source or device. Section 32.210 outlines the NRC safety evaluation and registration criteria and clarifies the regulatory responsibility of registration certificate holders of products for which the NRC evaluates and registers radiation safety information.

Current regulations only require that products used under a specific license issued in accordance with 10 CFR Part 30 be registered with the Commission. However, if registration of a product design is deemed necessary by NRC, the applicant needs to provide the information contained in 10 CFR 32.210 and the application will be evaluated in the same manner as all registration applications.

The products listed in Sections 4.1 through 4.5 are used by persons exempt from licensing requirements or used in accordance with a general license and NRC has determined that registration of the product design is necessary. However, in addition to the general registration criteria in 10 CFR 32.210, the regulations require that the products meet certain specific requirements. These specific requirements are listed in the appropriate section (Sections 4.1 through 4.5) and need to be addressed during the product evaluation.

Some specific-licensed products are required, by regulation, to meet certain specific requirements in addition to the general registration criteria provided in 10 CFR 32.210. The specific requirements for these products are listed in Sections 4.6 through 4.9 and need to be addressed during the product evaluation.

4.1 Self-Luminous Products Containing Tritium, Krypton-85, or Promethium-147 for use by Persons Exempt from Licensing Requirements

Under 10 CFR 30.19, persons are exempted from licensing requirements if the products are initially transferred in accordance with a license issued pursuant to 10 CFR 32.22. Therefore, the requirements for product evaluation are imposed on the person licensed to manufacture or initially transfer the product. Specific requirements, imposed on the product design, that must be addressed during the product evaluation are listed below:

Area to be Addressed	Applicable 10 CFR Regulations
Design	30.19(a) & (c), 32.22(a)
Maximum Radiation Levels	32.22(a)(2)(vi)
Maximum Dose Commitments	32.22(a)(2)(xiii) & (xiv)
Labeling	32.25(b)[(1)]

Figure 4.1 Watches. *Watches are products distributed to persons exempt from licensing under 10 CFR 30.19.*

Figure 4.1 Aiming Sights. *Aiming sights are products distributed to persons exempt from licensing under 10 CFR 30.19.*

Figure 4.2a Smoke and Chemical Agent Detectors. *Smoke and chemical agent detectors are products distributed to persons exempt from licensing under 10 CFR 30.20.*

Figure 4.2b Smoke and Chemical Agent Detectors. *Smoke and chemical agent detectors are products distributed to persons exempt from licensing under 10 CFR 30.20.*

4.2 Gas and Aerosol Detectors Containing Byproduct Material for use by Persons Exempt from Licensing Requirements

Under 10 CFR 30.20, persons are exempted from licensing requirements if the products are initially transferred in accordance with a license issued pursuant to 10 CFR 32.26. Therefore, the requirements for product evaluation are imposed on the person licensed to manufacture or initially transfer the product. Specific requirements, imposed on the product design, that must be

addressed during the product evaluation are listed below:

Area to be Addressed	Applicable 10 CFR Regulations
Design	30.20(a), 32.26[(2)]
Maximum Radiation Levels	32.26(b)(6)
Maximum Dose Commitments	32.26(b)(13) & (14)
Labeling	32.29(b)[(3)]

4.3 Devices Used Under the General License in 10 CFR 31.5

Under 10 CFR 31.5, persons may use certain devices in accordance with a general license provided the devices were manufactured or initially transferred in accordance with a license issued pursuant to 10 CFR 32.51. The devices used under the general license include devices designed for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere. The requirements for product evaluation are imposed on the person licensed to manufacture or initially transfer the product. Specific requirements, imposed on the product design, that must be addressed during the product evaluation are listed below:

Area to be Addressed	Applicable 10 CFR Regulations
Design	31.5(a), 32.51(a)(2)(I)
Maximum Dose Commitments	32.51(a)(2)(ii) & (iii)
Labeling	32.51(a)(3)
Leak Testing	32.51(b)
Testing and Servicing	32.51(b) & (c)

Figure 4.3a 10 CFR 31.5 General License. *Gas chromatographs devices are products used under 10 CFR 31.5 general license.*

Figure 4.3b 10 CFR 31.5 General License. *Density gauge devices are products used under 10 CFR 31.5 general license.*

Figure 4.3c 10 CFR 31.5 General License. *Static elimination devices are products used under 10 CFR 31.5 general license.*

4.4 Luminous Safety Devices Used in Aircraft Under 10 CFR 31.7

Under 10 CFR 31.7, persons may use luminous safety devices containing tritium or promethium-147 in accordance with a general license provided the devices were manufactured or initially transferred in accordance with a license issued pursuant to 10 CFR 32.53. Therefore, the

requirements for product evaluation are imposed on the person licensed to manufacture or initially transfer the product. Specific requirements, imposed on the product design, that must be addressed during the product evaluation, are listed below:

Area to be Addressed	Applicable 10 CFR Regulations
Design	32.53(c) & (d)
Prototype Testing	32.53(d)(4), 32.101
Labeling	32.54
Quality Control	32.55, 32.110

Figure 4.4a 10 CFR 31.7 General License. *Safety devices, such as exit signs, containing tritium or promethium-147 and used in aircraft may be used under 10 CFR 31.7 general license.*

Figure 4.4b 10 CFR 31.7 General License. *Safety devices, such as exit signs, containing tritium or promethium-147 and used in aircraft may be used under 10 CFR 31.7 general license.*

4.5 Ice Detection Devices Containing Strontium-90

Under 10 CFR 31.10, persons may use ice detection devices containing strontium-90 in accordance with a general license provided the devices were manufactured or initially transferred in accordance with a license issued pursuant to 10 CFR 32.61. Therefore, the requirements for product evaluation are imposed on the person licensed to transfer the product. Specific requirements, imposed on the product design, that must be addressed during the product evaluation are listed below:

Area to be Addressed	Applicable 10 CFR Regulations
Design	32.61(c) & (e)
Labeling	32.61(d)
Prototype Testing	32.61(e)(4), 32.103
Quality Control	32.61(e)(5), 32.62, 32.110

4.6 Radiography Equipment

Persons specific licensed to perform industrial radiographic operations are only authorized to use equipment that meets the requirements of 10 CFR Part 34. The vendor or custom user of the equipment may demonstrate that the equipment meets these requirements as part of the evaluation and registration of the equipment. Therefore, during an evaluation of radiography equipment, the items listed below must be addressed:

Area to be Addressed	Applicable 10 CFR Regulations
Design	34.20(a), 34.22
Leak Testing	34.27
Labeling	34.20
Prototype Testing	34.20
Maximum Radiation Levels	34.20, 34.21

Figure 4.5 Radiography Equipment. *Radiography equipment, such as the equipment shown above, must meet the requirements of 10 CFR Part 34.*

4.7 Well-Logging Equipment

Persons specifically licensed to perform well-logging operations are only authorized to use equipment that meets the requirements of 10 CFR Part 39, Subpart C[(4)]. One such requirement is that the licensed material be as insoluble and nondispersible as practicable. The vendor or custom user of the equipment may demonstrate that the equipment meets the requirements as part of the evaluation and registration of the equipment. Therefore, during an evaluation of well-logging equipment, the items listed below must be addressed:

Area to be Addressed	Applicable 10 CFR Regulations
Labeling	39.31(a)
Leak Testing	39.35
Design	39.41(a)(1) & (2)
Prototype Testing	39.41(a)(3)

Figure 4.6 Well-Logging Operations. *Sealed sources used in well-logging operations must meet the requirements of 10 CFR Part 39.*

4.8 Irradiators

Persons specifically licensed to use sealed sources in irradiators are only authorized to use sealed sources that meet the requirements of 10 CFR 36.21. One such requirement is that the licensed material be as insoluble and nondispersible as practicable if used in a wet-source-storage or wet-source-change irradiator. The vendor or custom user of the sealed sources may demonstrate that the sealed sources meet the requirements as part of the evaluation and registration of the sealed source. Therefore, during an evaluation of irradiator sources, the items listed below must be addressed:

Area to be Addressed	Applicable 10 CFR Regulations
Design	36.21(a)(2), (3), & (4)
Leak Testing	36.59

Area to be Addressed	Applicable 10 CFR Regulations
Prototype Testing	36.21(a)(5)

Figure 4.7a Irradiators. NRC evaluates (a) category I (self-shielded) irradiators used in category IV (Panoramic, wet source storage) irradiators.

Figure 4.7b Irradiators. NRC evaluates (b) sealed sources used in category IV (Panoramic, wet source storage) irradiators.

4.9 Sealed Sources and Devices for Medical Use

In accordance with 10 CFR 35.49, only sealed sources and devices that are manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to 10 CFR 32.74 may be used for medical uses. The vendor of the sealed sources may demonstrate that the sealed source meets the requirements as part of the evaluation and registration of the sealed source or device. Therefore, during an evaluation of medical sealed sources or devices, the items listed below must be addressed:

Area to be Addressed	Applicable 10 CFR Regulations
Labeling	32.74(a)(2)(viii) & (a)(3)
Leak Testing	32.74(b)

One exception to the above requirement is teletherapy sources. Specifically, teletherapy sources do not need to meet the requirements of 10 CFR 32.74. However, 10 CFR 35.49(b) indicates that they do need to be manufactured and distributed in accordance with a license issued pursuant to 10 CFR Part 30.

5 General Policies and Procedures

5.1 Sealed Source and Device Designs that do not Require Evaluation by IMNS

10 CFR 30.32(g) applies to all sealed sources and devices used by NRC specific licensees and requires evaluation of the product by NRC. However, the possession and use of certain products does not require the evaluation and registration of the product by IMNS. Specifically, evaluation and licensing of the following products should be handled as indicated below by the license reviewer:

5.1.1 Calibration and Reference Standards

Calibration and reference sources may be licensed without evaluation review by IMNS if the sources do not exceed the following:

- For beta and/or gamma emitting material - 3.7 MBq (100 microcuries) or ten times the

quantity specified in Section 30.71, Schedule B, 10 CFR 30, whichever is greater.

- For alpha emitting material - 0.37 MBq (10 microcuries).

The above values were chosen because they represent minimal hazard to public health and safety. To license these sources, license reviewers need to identify the isotope in Item 6 of the materials license, use the statement "calibration or reference sources" in Item 7, and state the maximum quantity for each source in Item 8. Both possession and distribution to specific licensees may be authorized.

Figure 5.1 Calibration and Reference Sources. *Calibration and reference sources may not need evaluation and registration by IMNS.*

5.1.2 Products used in Research and Development or by Broad Scope Licensees

Sealed sources or devices containing sealed sources that are intended only for use under research and development or broad scope licenses need not be evaluated by IMNS if the licensing reviewer has made a determination that:

- for unregistered sources, or registered sealed sources not possessed and used in accordance with the registration, - the licensee is qualified by sufficient training and experience and has sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in unsealed form.

- for registered sealed sources contained in unregistered devices - the licensee is qualified by sufficient training and experience and has sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in unshielded form.

If a research and development or broad scope licensee wishes to transfer a sealed source or device to another specific licensee, then the recipient must meet the criteria listed above or the sealed source or device must be registered in accordance with 10 CFR 32.210 prior to transfer.

License reviewers should utilize the following standard license condition for those recipients of the registered sealed source contained in unregistered devices:

"The licensee shall use only sealed sources for which a sealed source registration certificate has been issued by the U. S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210(e) or an Agreement State. Possession and use of the sealed sources used must adhere to the conditions and limitations of the registration certificate."

5.1.3 Custom Sealed Sources or Devices

Sealed sources or devices containing sealed sources built to the unique specifications of a given user (custom) need not be sent to IMNS for evaluation if: (a) they contain less than 7.4 GBq (200

millicuries) of radioactive material or less than 740 GBq (20 curies) of tritium, and (b) the licensing reviewer has made a determination that the applicant is qualified by training and experience and has adequate facilities and equipment to safely use and handle the requested quantity of radioactive material in unsealed form. Thus, the applicant would not have to rely on the intrinsic safety of the sealed source or device to demonstrate compliance with 10 CFR 30.33. Custom sealed source and devices which contain an activity greater than that listed above must be submitted to IMNS for evaluation and registration.

To license these custom sealed sources and/or devices, license reviewers need to identify the isotope in Item 6 of the material license, use the statement "custom source" (for unregistered sources) or "sealed source" (for registered sealed sources) including a unique identifier (e.g., drawing or model number), if possible, in Item 7, and state the maximum quantity of radionuclide per source or device in Item 8. In Item 9 (authorized use) license reviewers need to describe, as clearly as possible, the actual use of the custom source or device. Examples: "For use in a Model A analyzer custom built for the licensee by ABC Company in Notown" or "Custom source for use in XYZ Model 100 gauge."

The authorization to use sources or devices described above, that have not been evaluated and registered by IMNS, apply to only to the custom user of the product.

5.2 Custom Users

A user of a product that is manufactured in accordance with the unique specifications of, and for use by, a single applicant is considered a custom user. Custom users are specifically identified on the first page of registration certificates. The request for the safety evaluation and registration of the product may be made by the custom user or vendor. Regardless of the applicant, the custom user is required to meet all commitments made in the application and registration certificate. Typically, no more than two different NRC or Agreement State licensees may be custom users of, and may register, the same product. However, a custom user may acquire and/or use more than one product.

5.3 As Low as is Reasonably Achievable

The Commission's requirements to establish programs, procedures, and engineering controls for achieving doses that are as-low-as-is-reasonably-achievable (ALARA) are included in 10 CFR 20.1101. Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Is Reasonably Achievable," explains the NRC's position on this subject. Although these requirements apply to possession and use of radioactive material, applicants should consider the ALARA philosophy when designing and constructing sealed sources or devices to avoid unnecessary exposures during installation, maintenance, repair, and use of the sealed source or device. Regulatory Guide 8.10 may be useful to applicants for establishing and following an ALARA philosophy during the design of a sealed source or device.

5.4 Naturally Occurring or Accelerator-Produced Radioactive Material

Agreement and Non-Agreement States issue registration certificates for sealed sources or devices containing Naturally occurring or Accelerator-produced Radioactive Material (NARM). Copies of these registration certificates are provided to IMNS by the States. IMNS does not perform a review of these certificates, but does incorporate these certificates into the national registry. Copies are forwarded to the NRC regions, all Agreement States, and appropriate Federal and international agencies as a service to the States. This practice replaces the United States Food and Drug Administration (FDA) "Radioactive Materials Reference Manual." Questions concerning NARM certificates should be directed to OSP, the State, or FDA.

As a general rule, the NRC does not accept applications for radiation safety evaluation and registration of sealed sources or devices that contain NARM. Exceptions to this general rule include sealed sources or devices that contain material that can be reactor or accelerator produced (e.g., cadmium-109), or sealed sources or devices that contain NARM commingled with byproduct material, in either the same or separate encapsulations (e.g., moisture density gauges containing radium-226 and cesium-137).

5.5 Foreign Vendors

Foreign vendors present a unique situation for the NRC in that the NRC has no jurisdiction over foreign entities. The NRC has historically followed the regulation of 10 CFR Part 110 since a foreign vendor is required to establish an address in the United States to which the NRC can correspond and serve papers as necessary to accomplish its mission. In addition, the NRC inspects the United States distributor of the product and may occasionally audit foreign vendors to determine if the products distributed are in accordance with the statements made in support of the registration certificates.

Figure 5.2 Map of the World. *Foreign vendors are required to establish an address in the United States to which the NRC can correspond and serve papers as necessary to accomplish its mission.*

5.6 Use of International or Foreign Standards

In some cases, an applicant may wish to test a product in accordance with an international or foreign standard. In order for the NRC to find this acceptable, the applicant must first demonstrate and the reviewer confirm that the standard meets or exceeds any specific regulatory requirements (e.g., compliance with American National Standards Institute (ANSI) N432-1980 for radiography equipment). The applicant and reviewer must each review the requirements and acceptance criteria of the standard based on the normal and likely accident conditions associated with use, handling, storage, and transport of the product to determine if the standard is acceptable. The foreign or international standard may be compared with an applicable United

States standard in determining the acceptance of the standard. This may include professional judgement on the parts of the applicant and reviewer.

If a foreign standard is used, the applicant must submit copies of both the original and English translation of the standard.

5.7 FDA-NRC Memorandum of Understanding

The FDA and the NRC signed a Memorandum of Understanding (MOU)[(5)] to coordinate existing FDA and NRC regulatory programs for medical devices, drugs, and biological products that make use of byproduct, source, or special nuclear materials. The principal statute under which the FDA regulates devices is the Federal Food and Drug and Cosmetic Act, as amended by the Safe Medical Devices Amendments of 1976, the Safe Medical Devices Act of 1990, and the Medical Devices Act of 1992.

Under the MOU, the agencies agree to promptly inform each other whenever they receive a report or otherwise become aware of any potential public health problems involving products of mutual regulatory concern. Further, the agencies will share information to the extent practicable. For IMNS, this includes information used by the NRC for product evaluations and approvals, and any incidents involving product failures. The FDA must be notified in writing when the NRC begins an evaluation of a medical product, whether it is for a new product or for an amendment to an existing product. The notification should include the company, product model number, and the scope of the request. NRC policy precludes the approval of a medical sealed source or device unless the applicant has submitted a copy of the pre-marketing approval [510(k)] issued by FDA. If the pre-marketing approval is not submitted with the application, the applicant will be instructed to contact the FDA and obtain the appropriate approval.

Applicants needing information on FDA requirements may contact:

	Food and Drug Administration Office of Compliance HFZ-300 2098 Gaither Road Rockville, MD 20850 (301) 594-4692

5.8 Computer Software

NRC safety evaluations concentrate only on those systems that control fundamental safety processes such as checking an interlock, source or shielding position, and the functionality of position indicators. Software applications that deal with process controls are not part of the product evaluation. The reviewer will determine that if such systems fail (e.g., a power failure),

the sealed source or shielding would return to, or remain in, the fully shielded position. Medical applications involving computer software and patient planning systems are, in general, within FDA jurisdiction and FDA is responsible for any necessary review of the software.

Figure 5.3 Computer Software. *Safety evaluations concentrate only on those systems that control fundamental safety processes such as checking an interlock, source or shielding position, and the functionality of position indicators.*

Applicants should note that some computer systems and software programs, including embedded microprocessors, currently in use, and some systems and programs being distributed, may experience problems as a result of the turn of the new century. Applicants should evaluate the effects of the problems on the normal operation and the operation of the safety features of their equipment.

5.9 Registration Certificate Revocation

If it is determined that a sealed source or device evaluated by the NRC may pose an undue hazard when used in accordance with the conditions of the registration certificate and corrective actions cannot be implemented or agreed upon between the registration certificate holder and the NRC, the NRC may modify or remove the registration certificate from the national registry and may issue orders modifying licenses to all persons licensed by the NRC to use the sealed source or device. IMNS will also notify OSP so that the Agreement States are made aware of the NRC actions concerning the sealed source or device.

5.10 Incidents

Incidents involving products evaluated and registered by the NRC are assessed to determine whether the integrity or adequacy of the product was compromised. The assessment involves a re-evaluation of the product to determine its integrity and adequacy, taking into account the causes of the incident. If it is determined that a generic product fault exists, the registration certificate holder will be notified and appropriate actions, affecting both products currently in use and newly manufactured products, will be taken. In addition, the NRC will re-evaluate similar products to ensure they are not susceptible to the same type of faults.

Usually, incidents caused by abnormal or unauthorized use of the product would be considered licensing issues and would not require a re-evaluation of the product.

Some information concerning incidents involving products evaluated by the NRC is kept on file by IMNS for use in performing future evaluations of the products involved and products similar to those involved. However, the Office of Analysis and Evaluation of Operational Data is the NRC Office responsible for compiling, tracking, and analyzing incidents and reports.

5.11 Proprietary Information

Registration certificates and information contained in the background files for the registration certificates, such as applications, may be made available to the public. Persons may request access to this information in accordance with 10 CFR 9.23.

Proprietary information (i.e., information not to be disclosed to the public) should not be included in an application unless it is the only means to adequately describe the radiation safety properties of the product. If an application contains information marked as "proprietary," "confidential," "restricted," or "is the express property of Company X," the reviewer needs to determine whether the information is necessary to perform the safety evaluation. If the information is not necessary, it should be returned to the applicant.

If the information is necessary, the reviewer needs to ensure that the applicant has submitted a formal request, in accordance with 10 CFR 2.790, for withholding the information. The reviewer needs to evaluate the applicant's request for withholding against the requirements in 10 CFR 2.790 (Appendix B includes a checklist for requests for withholding information from public disclosure). If the request is denied, in whole or in part, the reviewer needs to give the applicant the option of withdrawing the information or application. If the applicant decides not to withdraw the information or application, the reviewer needs to notify the applicant in writing that the request for withholding has been denied and that the reviewer will disregard any references concerning the proprietary status of the information.

Any part of the application that the reviewer has determined should be withheld from public disclosure should be handled in accordance with Management Directive 12.6, "NRC Sensitive Unclassified Information Security Program" and the applicant should be notified in writing that the NRC plans to honor the request. However, the notification needs to inform the applicant that the NRC may have cause to review the determination in the future, for example, if the scope of a Freedom of Information Act request includes the information. In all review situations, if the NRC needs additional information from the applicant or makes a determination adverse to the initial determination, the applicant will be notified in advance of any public disclosure.

5.12 Transportation

This document does not cover detailed requirements for the transportation of devices and sealed sources. The NRC's transportation requirements are contained in 10 CFR Part 71, "Packaging and Transportation of Radioactive Material." 10 CFR Part 71 establishes:

- procedures and standards for NRC approval of packaging and shipping procedures for fissile material and for a quantity of licensed material in excess of a "Type A quantity" (i.e., exceeding A_1 or A_2 as defined in 10 CFR 71.4); and

- requirements for quality assurance, packaging, preparation for shipment, and transportation of licensed material.

Although an application for radiation safety evaluation of a sealed source or device as discussed

in this document is not expected to include a detailed description of packaging and transportation procedures to demonstrate compliance with 10 CFR Part 71, the applicant is expected to be familiar with the way those requirements apply to the sealed source or device and the action needed to ensure that transportation of the device is performed in accordance with applicable requirements.

Any vendor who has questions about the requirements for transportation may contact the appropriate NRC region or NRC's Transportation Safety and Inspection Branch, Spent Fuel Project Office, at (301) 415-8502 to obtain assistance.

Figure 5.4 Packaging and Transportation. *Registration certificate holders must meet all NRC and DOT requirements for packaging and transporting sealed sources and devices.*

Although IMNS does not evaluate packaging or transportation requirements during sealed source or device evaluations, IMNS does evaluate the effects the packaging or transportation has on normal use and operation of the product as part of the evaluation. Specifically, IMNS evaluates the effects of normal conditions experienced during transport (e.g., extreme temperatures, vibration) on the sealed source or device. Applicants should consider these effects during the design of the products and packaging for transport.

6 How to File

No special form is required for applications for sealed source or device evaluations. However, to facilitate the review process, applicants for a sealed source or device evaluation are encouraged to do the following:

General/Format:

- Be sure to review the applicable regulations and use the most recent guidance, including this document, in preparing an application.

- Submit all documents, including all drawings if practicable, printed, on standard 8-1/2 inch x 11 inch paper. If submission of larger documents is necessary, they should be folded to 8-1/2 inch x 11 inch.

- All pages in an application should be numbered consecutively. If revisions are necessary after an application has been submitted, revised or replacement pages should be submitted and should show the date of revision or revision number. Supplemental pages submitted for insertion should be indicated alphanumerically (e.g., 12a, 12b, etc.).

- Submit an original, signed application and one additional copy. Retain a copy of the your registration application for future reference.

- Applicants may include a copy of their submittal on 3.5 inch disk in WordPerfect format.

Content:

- Complete the "Summary Data" section of Appendix C, "Application and Review Checklist."

- Attach the balance of the application to the "Summary Data" information. The order of the information in the application should correspond to the appropriate sub-section in Section 10.

- Use the "Checklist" included in Appendix C as a guide to determine whether all necessary information has been provided.

- The application should also include a drawing(s), no larger than about 4 inch x 6 inch, that may be included in the registration certificate, and that provide an overall representation of the product and its safety features.

- When drawings, operating manuals, descriptive sales literature, or similar documents are submitted as part of an application, they should be identified clearly as being part of the application. This might be done by marking the materials individually and listing them on a cover sheet for the application or listing them as enclosures to the letter that transmits the application.

- Avoid submitting proprietary information unless it is absolutely necessary.

- The application should include a clear, concise presentation of the information necessary for the evaluation, avoiding ambiguous and conflicting statements and wordy descriptions that do not contribute to a technical review.

- Terms included in the application should be used as they are defined in NRC regulations and national consensus standards, as applicable. All abbreviations and acronyms should be defined.

Engineering Drawings:

- All drawings should have a drawing number, revision number, company name, title, scale, and date. References to parts or other drawings should be clearly indicated.

- If drawings have been reduced or enlarged, this should be clearly indicated.

- All drawings should include one or several isometric projection diagrams showing components pertinent to radiation safety such as shielding material, shielding thickness, on-off mechanism, on-off indicator, label location, assembly methods, source mounting and security, and dimensions, tolerances, and materials of construction.

- Engineering drawings, must be in English. To facilitate preparing an application on a product manufactured outside the United States, the applicant may elect to write or otherwise affix the English translation directly on an engineering drawing.

It may be advantageous to submit a product (without radioactive material) or a part of a product with an application. For example, a vendor of radiography equipment may elect to submit a "pigtail" connector (used to join the source assembly to the drive cable) as a means of clarifying the related engineering drawings and operating instructions. Large pieces of equipment should not be submitted because of handling and storage limitations at the NRC offices.

All license applications will be available for review by the general public in the NRC's public document room. If it is necessary to submit proprietary information, follow the procedure in 10 CFR 2.790. See Section 5.10 of this NUREG for additional details.

Applications may be scanned or put through an optical character reader to convert them to electronic format. To assist with the conversion of the application to electronic media, applicants are requested to follow these suggestions:

- Submit printed or typewritten, not handwritten, text on smooth, crisp paper that will feed easily into the scanner.

- Choose typeface designs that are sans serif, such as Arial, Helvetica, Futura, Univers; the text of this document is in a serif font called Times New Roman.

- Choose 12-point or larger font size.

- Avoid stylized characters such as script, italic, etc.

- Be sure the print is clear and sharp.

- Be sure there is high contrast between the ink and paper (black ink on white paper is best).

7 Where to File

Applicants located in states or territories subject to NRC jurisdiction wishing to register a sealed source or device may file an application with the NRC by submitting the application to:

	United States Nuclear Regulatory Commission Materials Safety Branch Division of Industrial and Medical Nuclear Safety Washington, DC 20555-0001

Please note that the above address is different from that of the appropriate NRC region to which persons would apply for authority to possess and use radioactive material under a manufacturing and distribution license.

The above address cannot accept mail requiring the receiver's signature (e.g., express mail). Mail requiring the receiver's signature should be sent to:

	United States Nuclear Regulatory Commission Materials Safety Branch Division of Industrial and Medical Nuclear Safety Two White Flint North 11545 Rockville Pike North Bethesda, MD 50852

Applicants in locations subject to Agreement State jurisdiction wishing to apply for safety evaluation and registration of a sealed source or device should file the application with the appropriate Agreement State agency, not the NRC. See Section 2 for additional information concerning filing applications with Agreement States.

8 Registration Fees

Each application for which a fee is specified, including applications for new registration certificates and registration certificate amendments, must be accompanied by the appropriate fee. Refer to 10 CFR 170.31 to determine the amount of the fee. For applicants for sealed source and device evaluations, the appropriate fee categories are 9A, 9B, 9C, and 9D. The registration certificate or amendment will not be issued until full payment of the fee has been received.[(6)] Once the technical review process has begun, no fees will be refunded; application fees will be charged regardless of the NRC's disposition of an application or the withdrawal of an application.

Most NRC registration certificate holders are also subject to annual fees; refer to 10 CFR 171.16. Consult 10 CFR 171.11 for additional information on exemptions from annual fees and 10 CFR 171.16(c) on reduced annual fees for registration certificate holders that may qualify as "small entities."

Direct all questions about NRC's fees to the Office of the Controller (OC) at the NRC headquarters in Rockville, Maryland, (301) 415-7554. You may also call NRC's toll free number (800) 368-5642 and then ask for extension 415-7554.

9 Document Flow

9.1 Application Receipt and Assignment to a Reviewer

Requests for safety evaluations of sealed sources or devices usually are submitted by the applicant directly to IMNS. However, applications may be submitted to other NRC sections or Offices (e.g., as part of a licensing action) and forwarded to IMNS as a technical assistance request. For example, the NRC regions and other sections within IMNS may receive requests as part of a license request, or OC may receive a request to make a registration certificate inactive. The processing of the application is the same in all cases.

NRC staff submitting technical assistance requests for sealed source and device evaluations to IMNS should use NRC Form 567, "Request for a Sealed Source Device Evaluation." The requester needs to follow the instruction block at the top of the form for specific detail on how and what to submit.

When IMNS receives an application, an acceptance review is performed to determine whether there is sufficient information to initiate a review. If there is sufficient information to initiate a review, the applicant is sent a letter acknowledging receipt of the application; if not, the entire package is returned to the applicant for resubmission of a complete application.

Applications are logged into the sealed source and device action tracking system where they await assignment to a reviewer. Each action is assigned a unique tracking number. Assignment to a reviewer is determined on a first-in basis. An application may be assigned a higher priority

based on the dire need for the product to protect public health and safety, the product providing a currently unavailable benefit to society, or commercial hardship that is likely to be experienced by the applicant if the evaluation process is delayed. Requests for higher priority should include adequate justification.

While an application is awaiting assignment to a reviewer, a copy of the cover letter to the application and the NRC Form 567 is sent to the OC for verification that the appropriate application fees have been received. OC will return NRC Form 567 to IMNS indicating whether the appropriate fees have been collected. IMNS may start an evaluation of a sealed source or device before fees are collected, however, a final approval of the product will not be issued until the application fees are paid in full.

9.2 Reviewer's Responsibilities

The reviewer is responsible for performing the technical evaluation of the product, ensuring the product meets all applicable standards and regulations, corresponding with the applicant to obtain additional information, if necessary, generating the registration certificate, and ensuring the application is reviewed and signed by two persons having signature authority. In addition, the reviewer needs to identify any complex policy issues and bring them to management's attention.

In some cases, the adequacy of an element of the product design may not be readily evident. As a result, it may be necessary for the reviewer to exercise professional judgment regarding the adequacy and safety of the product design. Such judgment should be discussed with the applicant and included in a note from the reviewer to the registration file. A copy of the note to the registration file should be provided to the applicant.

Once the evaluation and registration are complete, the registration certificate, including cover letter to the applicant and technical assistance request response, if applicable, and all information used in support of the evaluation, are forwarded to the registration assistant for distribution and filing.

See Section 2 concerning the NRC review of Agreement State registration certificates.

9.3 Distribution of Completed Certificates

The registration assistant processes distribution of all registration certificates issued by the NRC and the Agreement States.

After the registration certificate is completed and the package is forwarded to the registration assistant, all correspondence between the NRC and the applicant is sent to the Document Control Desk (DCD). Copies of Agreement State certificates also are forwarded to DCD. DCD ensures that the information is included in Nuclear Documents System and the Public Document Room.

The registration assistant distributes copies of all registration certificates to the NRC regions, all

Agreement States, other Federal agencies, and international agencies. The NRC File Center ensures that original NRC registration certificates are maintained in the registration folders and that a master set of copies of the certificates are maintained and easily accessible to IMNS.

9.4 Inclusion in the Sealed Source and Device Computerized Registration System

Once issued, the registration certificate is added to the sealed source and device computerized registration system. The information included on the first page of the registration certificate is included in the system and certificate information can be located by searching on any item that is included in the first page of the certificate (see Section 12.2).

10 Contents of the Application and the Review Process

Applicants requesting safety evaluations and persons who evaluate the adequacy of products must address the following items to verify sufficient information is submitted and determine whether the design of the product is adequate for its proposed uses.

Applicants are encouraged to follow the instructions in Section 6 and use Appendix C as a guideline when submitting applications. Applicants should complete the "Summary Data" section of the appendix and use the "Checklist" to ensure that they have addressed all items listed in this section. The balance of the application should be attached to the copy of the appendix. Reviewers should use the checklist to verify the applicant has addressed all items listed in this section.

It should be noted that certain regulations include specific requirements applicable to evaluation and registration of products. Section 4 lists these regulations and each regulation also is listed at the end of the applicable topic of this section. The regulatory requirements take precedence over the general guidance provided in this section. Applicants must ensure, and reviewers verify, that all regulatory requirements are met.

The checklist is not considered an all inclusive review document. It is designed to highlight important aspects of the application. Further detail and review of specific areas of the applications may be necessary.

10.1 Summary Information

Manufacturer and Distributor

Applications must include the complete names and addresses of both the manufacturer and distributor of the product. The same person may be both the manufacturer and distributor. However, if different, the distributor should be the person applying for the evaluation. The distributor will be responsible for meeting the requirements associated with the registration,

whether the information is supplied by the distributor or by the manufacturer on behalf of the distributor.

Custom User

Applications must indicate whether the product is intended for use by a custom user. The customer user needs to be identified by name and complete address. See Section 5.2 for additional information concerning custom users.

A product specifically designed and constructed to the order of a single licensee may be considered a custom product. Since there is a single user of the product, the NRC can appropriately consider specific departures from accepted standards from the point of view of compensating qualifications or conditions of use for the particular licensee. Usually, these departures occur in the areas of prototype testing and quality control (QC) procedures.

Other Companies Involved

The application must include the name, complete mailing address, and function of all other companies involved in the manufacture and distribution of the product.

Model Number, Sealed Source or Device Type, and Principal Use Code

The application must clearly state the model number designation for the product. This model number will be listed on the registration certificate for the product and may be listed on licenses of persons applying to use the product. The model number is used by the NRC and Agreement States to uniquely identify the product.

An applicant may request to have a model listed as a series. In order to have the model listed as a series, there should be similarities in the design and construction of the products. Applicants should provide detailed engineering drawings of each basic source or device series containing overall dimensions, maximum and minimum dimensions, tolerances, materials of construction, and differences between models in the series.

The application needs to identify the sealed source or device type as used by the industry (e.g., level gauge, radiography device, self-shielded irradiator, teletherapy unit, etc.) and the principal use code that most accurately describes the product. A listing of principal use codes is included in Appendix E. This information assists applicants and reviewers in determining the applicable regulations, codes, and standards that affect registration of the product.

The application also needs to identify whether the device is intended to be used under a specific license, general license, either a specific or general license, or by persons exempt from licensing requirements. If applicable, the applicant and reviewer need to determine which general license or exemption applies for possession and use of the product. Information needed to make this determination must be provided by the applicant. This is discussed further under Section 10.2, which discusses the conditions of use of the product.

Radionuclides Used in the Product

The applicant must identify all radionuclides that will be used in the product and include the maximum requested activity for each, including loading tolerance. The application must also include the form of the byproduct material, including contaminates or impurities, if applicable. It is not necessary for applicants to provide information on contaminates or impurities that have little effect on the radiation levels from the sealed source or on how the sealed source will react under extreme environmental conditions.

For evaluations of devices, the applicant must identify whether the associated sealed source is currently registered. If so, the model number designation and the manufacturer or distributor of the sealed source, as listed on the registration certificate for the sealed source, must be identified.

If the sealed source is not currently registered, the sealed source must be registered separately or as part of the device. In either case, the applicant must submit sufficient information to register the sealed source and the reviewer must perform a complete evaluation of the sealed source. If the sealed source is registered as part of the device, the registration certificate for the device should note that the sealed source is not registered separately, is registered as part of the device, and is only approved for use in the device.

Leak Test Frequency

The applicant must provide the maximum time interval between leak tests to be performed on the product. Typically, products are required to be leak tested at intervals not to exceed 6 months. Leak test procedures must be capable of detecting the presence of 185 Bq (0.005 microcurie) of removable contamination.

Products containing only krypton-85, hydrogen-3 (tritium), radioactive gas, isotopes with half-lives of 30 days or less, beta- or gamma-emitting material of no more than 3.7 MBq (100 microcuries), or alpha-emitting material of no more than 370 kBq (10 microcuries) are exempt from periodic leak testing requirements. However, prior to initial distribution of the product, a leak test should be performed.

Devices may be approved with leak test intervals greater than 6 months if sufficient information is submitted to justify such a request. Current policy requires, for specific- or general-licensed products, the applicant to supply the information listed in 10 CFR 32.51(b) or 32.74(b)(1) for evaluation if a longer leak test interval is requested.

The following regulations should be referenced for additional information concerning leak testing:

Regulations	Applicability
10 CFR 32.51(b)	Devices used under the 10 CFR 31.5 general license

Regulations	Applicability
10 CFR 34.27	Sources and devices designed for use in radiography operations
10 CFR 39.35	Sources used in well-logging operations
10 CFR 36.59	Irradiator operations
10 CFR 32.74(b)	Sources or devices for medical use

Certification and Signature of a Management Representative

Individuals acting in a private capacity are required to date and sign the application. Otherwise, representatives of the corporation or legal entity filing the application should date and sign the application. **Representatives signing an application must be authorized to make binding commitments and to sign official documents on behalf of the applicant.** As discussed previously in Section 3 "Management Responsibility," signing the application acknowledges management's commitment and responsibilities for the regulatory requirements. **The NRC will return all unsigned applications for proper signature.**

- It is a criminal offense to make a willful false statement or representation on applications or correspondence (18 U.S.C. 1001).

- When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

10.2 Conditions of Use

The applicant must identify, and the reviewer evaluate, the intended use and users of the product and which standards, policies, and regulations are applicable. Applicable standards or regulations may specify prototype testing, labeling, design, maximum external radiation levels, maximum dose commitments, QC and quality assurance (QA), or leak testing requirements.

The intended use of the product should include descriptions of the types of users, the locations of use, the occasions when persons will be near the device and the frequency of these occasions, and the possibility that the device may be used as a component in other products.

The applicant and reviewer must also evaluate the likely environments to which the product will be subjected during normal use and likely accident conditions. Normal use and likely accident conditions should include those experienced during use, handling, storage, and transportation (extremes experienced during accident conditions during transportation need not be considered). The applicant and reviewer need to evaluate whether the product will be subject to extreme conditions of corrosion, vibration, impact, puncture, compressive loads, explosion, flooding, poor air quality, excessive high or low temperatures, change in temperature (i.e., thermal cycling), and cycling of the on/off mechanism.

The applicant should provide the estimated working life of the product. The reviewer should

evaluate the product's estimated working life to determine whether it is justified based on the information submitted. Inclusion of the working life of the product is important since registration certificates do not have expiration dates. Therefore, the working life provides an indication of when servicing or re-evaluation of a product integrity may be necessary.

10.3 Construction of the Product

Applicants need to describe construction aspects of the product including components of the product, materials of construction, dimensions, assembly methods, source containment and shielding, and operation of the product and its safety features. This should include a brief written description and summary of the construction aspects as well as specific, detailed descriptive data such as engineering drawings and product specification sheets.

The brief written description and summary of the construction aspects should include the overall operation of the product, identification of primary components and safety features, type of installation including method of attachment to its mounting if installed in a fixed location and means of relocation if portable, the primary construction materials used for the product's structure and integrity and for its safety features, accessibility of the radiation beam during use, the means of providing containment, security, and shielding of the radiation source including shutters or other movable shielding, location and operation of on/off or shielded/exposed indicators, and identification of other design features that protect the product from abuse or tampering. In addition, the identification of the components of the product and safety features should include a description of each's purpose, function, and operation. An overall drawing of the product identifying primary components and safety features and indicating overall dimensions is useful as a complement to the written description of the product and for providing an understanding of the operation of the product.

Detailed design and construction data should be sufficient to allow the reviewer to fully understand the construction and operation of the product and its components and safety features and to evaluate the product's safety and integrity. This should include complete annotated engineering design and/or construction drawings of all safety critical components, specification sheets, materials lists, and/or detailed written descriptions. In particular, mounting and integrity of the radioactive material or sealed source in the product must be described in detail. Drawings of safety critical parts and components should be fully dimensioned with tolerances, include identification of the safety critical parts, indicate the materials of construction or refer to a materials specification sheet or list, indicate fabrication and assembly methods, and include a drawing number and revision date or number. Parts critical to safety include those parts or components that provide primary containment, safety, and shielding of the radioactive material or sealed source. In addition, drawings and descriptions of non-safety critical components and parts that contribute to safety and/or integrity of the product should be provided. These drawings should include sufficient descriptive information to determine how the components contribute to the safety and/or integrity of the product, how the component is integrated with other components of the product, and determine if the non-safety critical components could degrade the effectiveness or usefulness of safety critical components.

All special design features that protect the product from abuse, control the hazard from direct or scattered radiation, and discourage unauthorized access to the source need to be adequately described. In addition, accessibility of the radiation beam during use, including the size of openings or air gaps that could allow any part of a human body to enter the radiation beam, and any protective measures, additional guards, or installation requirements designed to prevent accessibility of the radiation beam during use need to be addressed.

The reviewer must evaluate how the product is constructed and evaluate its integrity. The reviewer should be able to determine the construction of the product from the drawings and written description provided with the application. During the evaluation of product integrity, the reviewer needs to ensure the following:

The assembly methods (e.g., welds, bolts, screws), including size, materials, and spacing, and materials of construction of the device are sufficient to withstand normal use and likely accident conditions. These include being subjected to corrosive environments, vibration, impact, puncture, compressive loads, explosion, flooding, excessive high or low temperatures, and drastic changes in temperature (i.e., thermal cycling), and cycling of the on/off mechanism.

- If construction includes use of dissimilar materials, the materials are compatible and corrosion is not likely to occur because of contact between the unlike materials (e.g., corrosion is likely when you have direct contact between aluminum and steel, or depleted uranium and steel). In addition, the materials will not cause corrosive environments without direct contact (e.g., Teflon can break down when subjected to radiation and cause a corrosive environment for certain metals).

- The materials of construction (e.g., adhesives, lubricants, and gaskets) will not be detrimentally affected by exposure to radiation or expected conditions of use.

- The assembly methods would have no detrimental effects on the product during its fabrication (e.g., heat from welding a holder directly to the sealed source; securing the sealed source by tightening a screw or bolt against the wall of the sealed source).

- The fixed shielding will not move nor easily become dislodged from the device.

- The mounting of the sealed source is such that the sealed source will not unintentionally move during use nor become dislodged from the device, and the mounting sufficiently secures the sealed source against access by unauthorized users.

- All moving parts have adequate spacing to ensure they will not bind during use. The tolerances of the spacing between the parts should be such that likely changes (e.g., from bending, temperature changes causing expansion or contraction, introduction of foreign

materials) will not cause binding that may lead to unintentional exposure of the source.

- The device can be locked in the closed condition (source fully shielded) and cannot be locked in the open condition, if applicable.

- The device contains indicators that clearly identify whether the source shielding is in the open or closed position. If colors are used to identify the open or closed conditions, red should be used for the open condition where exposure could occur and green should be used for the closed condition where the source is "safe" in the shielded position.

- Sufficient safety interlocks, barriers, or guards are included to prevent access to the radiation beam and prevent exposures in excess of those specified in the regulations (the inclusion of barriers or guards should be included as reviewer notes to alert license reviewers).

- If pneumatic or hydraulic systems are used, there are appropriate filtration, relief valves, and operating pressures.

- The operation is designed to be fail-safe, that is, loss of power or a failure in the system would cause the shutter to return to, or remain in, the fully shielded position.

- If applicable, tamper-resistant hardware or assembly methods are used in the design of the device. Typically, this is required for devices used by general licensees and persons exempt from licensing.

- If applicable, the device is hermetically sealed from foreign materials or moisture.

- Sealed sources contain appropriate internal void spacing to ensure accurate leak testing results, if applicable. In addition, void spacing should allow for any thermal expansion of the materials.

Integrity of the product does not necessarily mean the product will perform its intended uses after being subjected to an accident or unlikely use conditions. However, the product should still ensure the byproduct material is not dispersed, the source capsule remains within the protective source housing, and the shielding integrity is not compromised. Typically, an increase in radiation of greater than 20% constitutes a compromise of the shielding integrity.

Appendix F includes a listing of references that may be useful in determining the adequacy and integrity of the product design.

The following regulations should be referenced for additional information concerning product designs:

Regulations	Applicability
10 CFR 30.19(a)&(c) 10 CFR 32.22(a)	Devices used under the 10 CFR 30.19 exemption.
10 CFR 30.20(a), 10 CFR 32.26	Devices used under the 10 CFR 30.20 exemption.
10 CFR 31.5(a), 10 CFR 32.51(a)(2)	Devices used under the 10 CFR 31.5 general license.
10 CFR 32.53(c)&(d)	Devices used under the 10 CFR 31.7 general license.
10 CFR 32.61(c)&(e)	Devices used under the 10 CFR 31.10 general license.
10 CFR 34.20 & 34.22	Sources and devices designed for use in radiography operations.
10 CFR 39.41(a)(1)&(2)	Sources used in well logging operations.
10 CFR 36.21(a)(2)(3)&(4)	Sources used in irradiator operations.

10.4 Labeling

Applicants must provide a description of the labeling of the product, including information contained on the label, materials of construction of the label, and how and where the label is attached. The labeling should be sufficiently durable to remain legible for the useful life of the product and, for devices, should be in a readily visible location. It is recommended that applicants provide samples or copies of the labels as part of the application.

The reviewer must verify that the application includes sufficient information concerning the labeling of the product. In addition to applicable regulatory requirements, applicants and reviewers should follow the guidelines outlined below for labeling of products:

- For Devices: Model Number, Serial Number, Isotope, Activity, Distributor's Name, Date of Assay, Trefoil Symbol, and the words “CAUTION - RADIOACTIVE MATERIAL.”[(7)] If applicable, the label should include a statement that it contains depleted uranium as shielding and include the total weight of the uranium. The label should also include limiting conditions of use or other information necessary for safe use of the product, such as servicing instructions, if applicable.

- For Sealed Sources: Should contain the same information as included on a device. However,

because of its size, all of the information may not fit. Therefore, it should contain as much of the information as possible with inclusion based on the importance of the information. The applicant should provide a justification for which information will be included. Final approval of the information is left to the discretion of the reviewer. Below is a listing, in no particular order, of the information, with a description of why the information may be important:

Trefoil Symbol and/or the Words "CAUTION - RADIOACTIVE MATERIAL" - This information is important if a source is found by a member of the public since it alerts the person finding the source that it contains radioactive material. The trefoil system is fairly well recognized. Therefore, for small sources where all the information may not fit, it is probably more important than the words "CAUTION - RADIOACTIVE MATERIAL."

Serial Number - The serial number can usually be traced back to determine the original activity, isotope, date of assay, and the last known user of the source. The current activity can be calculated, given this information. However, to trace back to this information, either the vendor or the last person possessing the source must be known and be in business. The serial number may be important for sources that would be stored in large quantities. This would assist the licensee in maintaining accountability of each source.

Distributor's Name or Logo - This may be important in trying to locate additional information concerning the source. However, if the serial number is not known or the distributor is no longer in business, this information may not be of much value.

Model Number - The NRC includes the sealed source model numbers in its sealed source and device computerized registration system. Therefore, the NRC could identify the distributor, possible isotopes, and maximum allowable activities, given the model number.

Isotope, Activity, Date of Assay - This information could assist trained personnel in responding to an incident involving the source. However, this information could be obtained from other information included on the source, as indicated above, or by analysis and from surveying radiation levels around the source.

The reviewer must evaluate whether the labeling is durable, will remain on the product, and will remain legible under normal use conditions through the working life of the product.

The preferred method of labeling sealed sources is engraving or laser etching the information. For devices, the preferred method is a metal label, with the information engraved or etched into the label, and the label attached to the device with screws or rivets. Other materials and methods may be acceptable depending on the likely environments in which the product will be used.

Labels must be placed so that they are easily visible to the users of a device and will remain attached to the part of the device that contains the radioactive material, that is, they are not attached to the detector housing or to a barrier or guard. The applicant may elect to have additional labels on the detector housing or on barriers or guards.

The reviewer needs to verify that the labeling does not misinterpret, misrepresent, or lead the

user into violating any applicable regulations. For example, devices distributed to specific licensees must not include statements concerning use of the device under a general license.

The following regulations should be reviewed for additional information concerning product labeling:

Regulations	Applicability
10 CFR 32.25(b)	Devices used under the 10 CFR 30.19 exemption.
10 CFR 32.29(b)	Devices used under the 10 CFR 30.20 exemption.
10 CFR 32.51(a)(3)	Devices used under the 10 CFR 31.5 general license.
10 CFR 32.54	Devices used under the 10 CFR 31.7 general license.
10 CFR 32.61(d)	Devices used under the 10 CFR 31.10 general license.
10 CFR 34.20	Source and devices designed for use in radiography operations.
10 CFR 39.31(a)	Sources used in well logging operations.
10 CFR 32.74(a)(2)(viii) & (a)(3)	Sources and devices for medical use.

10.5 Prototype Testing

An applicant must provide information that verifies that the product design will maintain its integrity when subjected to conditions of normal use and likely accident conditions. Normal use and likely accident conditions should include those experienced during installation, use, handling, maintenance, storage, and transportation (only normal conditions during transportation need to be considered). Applicants need to determine an appropriate method to demonstrate the product's ability to maintain its integrity when subjected to conditions of normal use and likely accident conditions. This may include:

- Testing a prototype of the product. A prototype product must be a complete representation of the final product that includes all safety features, shielding, safety markings (if appropriate), and any accessory features or mounting that may have a detrimental effect to the safety and integrity of the product when subjected to normal or likely accident conditions. Prototypes must be constructed from the same materials and to the same dimensions and tolerances as the final product, but may be a scale representation of the final product. Any variations of the prototype product from the final product must be analyzed for the effect to the test results the change would be expected to cause (see engineering analysis below).

- Performing an engineering analysis. An engineering analysis consists of a detailed, systematic

analysis of the design and materials of construction of the product and the processes used in the manufacturing of the product to determine the product's ability to maintain its integrity when subjected to normal and likely accident conditions. The analysis may consist of calculations, modeling, sample testing, and evaluation. In addition, when evaluating products for which an industry standard is applicable, an engineering analysis may be used to demonstrate that the item would successfully pass the standard tests, if it were subjected to the tests. The conclusions of an engineering analysis should be fully justified with supporting documentation describing the analysis and including calculations or other applicable reference material.

- Operational history of the product. Operational history includes identical devices (excluding accessory equipment that has no effect on the safety or integrity of the product) used in equivalent or more severe conditions of normal use. This typically includes products used in the United States as a custom product or in another country. Operational history should include the environmental and operating conditions, numbers of cycles per year, the results of any known accident conditions, the results and root causes of any known product failures, and the years of use of the product. Operational history must be sufficient to demonstrate that the product would be expected to operate safely and maintain its integrity during the product's intended normal conditions of use. In addition, if operational history is sufficiently comprehensive, it may also be used to demonstrate product integrity for likely accident conditions. However, a product's operational history would not be sufficient to demonstrate its ability to operate safely or maintain its integrity if it has never been subjected to the extremes of expected normal use or likely accident conditions.

- Comparison to a similar or equivalent model previously reviewed and registered. Information concerning a similar or equivalent product may be used to demonstrate safety or integrity of the requested product, if the design of the similar or equivalent product and its intended normal and likely accident conditions of use are identical or similar to the requested product or can be related (through engineering analysis) to the requested product's conditions of use. In addition, prototype testing of the similar product may also be submitted if it can be related to the requested product. The comparison should contain the information on the similar or equivalent product including prototype testing, applicable engineering analyses, or operational history and a detailed discussion and analysis of how this information relates to the requested product. In addition, the comparison must demonstrate that the requested product's ability to operate safely and maintain its integrity is equivalent to or more robust than the previously-approved product, or that the differences between the products are such that the integrity and safety would not be affected.

Regardless of which approach the applicant chooses to pursue, the reviewer must evaluate whether the applicant has adequately demonstrated that the product will maintain its integrity during normal use and likely accident conditions, and whether the information adequately addresses all concerns about the source or device's integrity when used in a way the applicant has defined as the normal conditions of use.

If the product is registered for use by a custom user, prototype testing may not be required. This is typical in a situation where only a limited number of units will be manufactured, usually one or two. Therefore, it may not be feasible to manufacture and test a prototype product which may not be able to be used after testing. Since only one licensee is using the product, additional administrative controls can be implemented by the licensee.

Sources

Typically, for sealed sources, the NRC will only accept actual testing of a prototype unit to demonstrate integrity. This is because the sealed source is the primary containment of the radioactive material. The sealed sources should normally be tested in accordance with ANSI N542, "Sealed Radioactive Sources, Classification," or International Organization of Standardization (ISO) 2919, "Sealed Radioactive Sources, Classification." When reviewing the testing, the reviewer must evaluate the test methods, procedures, and conditions of the tests and acceptance criteria used by the applicant against the standard. Any variations must be evaluated.

In addition to testing in accordance with an ANSI or ISO standard, the applicant may need to perform additional testing to verify that the source will withstand the conditions of use. For example, long sources may need to be subjected to a bend test and applicants may need to verify a source design will withstand corrosive environments.

Depending on the wall thickness of a source, engraving or etching the labeling information may have a detrimental effect on the source integrity. For thin walled sources, the prototype source should include all engraved or etched labeling information prior to testing.

Devices

When evaluating a device, the reviewer must verify that the sealed source incorporated in the device has achieved the appropriate ANSI N542 or ISO 2919 classification for its intended use and be authorized for the activity to be loaded. The registration certificate for the sealed source should include its classification.

Devices should be tested in accordance with applicable industry and consensus standards. A listing of applicable standards is included in Appendix G.[(8)] If there is no applicable standard for a product, the applicant and reviewer, using professional judgement, need to ensure that the testing performed sufficiently simulates the conditions that may be expected during use, handling, storage, and transport of the product. The applicant and reviewer may obtain useful general guidance from a standard for a comparable source or device.

In addition to the testing recommended in the standards, the applicant and reviewer need to consider other potential use and accident conditions that may affect a particular device's integrity. Devices should be tested to demonstrate they will maintain their containment integrity and that the necessary safety features remain operable after being subjected to any conditions they are likely to experience.

The testing does not need to verify that a device will operate and perform its intended function after being subjected to accident condition testing. However, the product should still ensure the byproduct material is not dispersed, the source capsule remains within the protective source housing, and the shielding integrity is not compromised. Typically, an increase in radiation of greater than 20% constitutes a compromise of the shielding integrity.

Occasionally, an applicant may indicate that a product has been tested in accordance with a standard that has limited applicability in demonstrating that the product will perform adequately, from a radiological standpoint, during normal use and likely accident conditions. Some examples of such standards are Type 7A package testing, special form testing for sealed sources, and testing to Underwriters Laboratory standards. The reviewer should ensure that the applicant does not rely on this testing alone to demonstrate device integrity.

The following regulations should be referenced for additional information concerning prototype testing:

Regulations	Applicability
10 CFR 32.53(d)(4), 10 CFR 32.101	Devices used under the 10 CFR 31.7 general license.
10 CFR 32.61(e)(4), 10 CFR 32.103	Devices used under the 10 CFR 31.10 general license.
10 CFR 34.20	Source and devices designed for use in radiography operations.
10 CFR 39.41(a)(3)	Sources used in well logging operations.
10 CFR 36.21(a)(5)	Sources used in irradiator operations.

10.6 Radiation Profiles

The applicant should provide the maximum radiation levels around the product when it contains the maximum allowable quantity of each nuclide, or combination of nuclides. The applicant should include the maximum radiation levels on the surface of the product, at 5, 30, and 100 cm (2.0, 11.8, and 39.4 in.) from the product, and levels in the radiation beam (if the beam is accessible). If applicable, radiation levels should include when the device is in the open and closed conditions and when material is present in the measuring area. Doses during transient conditions and during other conditions of use, such as during calibration, may also need to be reported. The reviewer must verify that the applicant has provided the maximum radiation levels.

Figure 10.1 Radiation Profiles. *ANSI-538 suggests radiation profiles be provided as indicated above.*

Measured radiation levels are preferable, but calculated levels also are acceptable. If the

measured radiation levels are submitted, the reviewer needs to verify that the conditions under which the measurements were taken and the equipment used -- including type, window thickness, and sensitivity -- are acceptable for the nuclide and quantity included in the product. If calculated levels are submitted, the reviewer needs to verify the calculations were performed in accordance with acceptable methods or standards.

If the applicant is taking credit for external shielding or barriers or guards that restrict access to higher radiation areas, the radiation levels at, and at distances from, each barrier or guard need to be reported.

The reviewer needs to verify that radiation levels are reasonable. The levels for gamma emitters should be consistent with the inverse-square law and levels for non-gamma emitters should not. The reviewer also needs to assess whether levels that initially appear unreasonable, such as higher levels farther from the product, are possible because of scatter.

Even though 50μSv/hr (5 mrem/hr) at 30.5 cm (12 in.) is an industry goal that has been used for many years, in general, there are no maximum external radiation level limitations for sealed sources and specifically licensed devices. Ultimately, it is the responsibility of the user to ensure the product is used in accordance with 10 CFR Part 20, (e.g., the specific licensee is responsible for ensuring that persons do not receive doses in excess of the occupational limits or limits for members of the public and that occupational exposures are ALARA).

If a device is intended for use on a patient, the dose to the patient for a typical application should be provided. This will serve as a reference point in approving and licensing the product.

The following regulations should be referenced for additional information concerning radiation profiles and maximum dose commitments:

Regulations	Applicability
10 CFR 32.22(a)(2)(vi), (xiii), and (xiv)	Devices used under the 10 CFR 30.19 exemption.
10 CFR 32.26(b)(6), (13), and (14)	Devices used under the 10 CFR 30.20 exemption.
10 CFR 32.51(a)(2)(ii) &(iii)	Devices used under the 10 CFR 31.5 general license.
10 CFR 34.20 & 34.21(a)	Source and devices designed for use in radiography operations.

10.7 Quality Control and Quality Assurance

The applicant must provide details of the QC program that will be implemented to ensure that the product is manufactured and distributed in accordance with the representations made in the application, and the statements contained in the registration certificate for the product. At a minimum, the QC program needs to ensure that: (1) the materials of construction and the final

assembly meet the design specifications; (2) the final product is leak tested; (3) a final radiation profile is performed; (4) a test that verifies the product operates as intended, including all safety functions, is performed; and, (5) a visual and mechanical inspection of components that are considered critical to safety or are expected to be susceptible to failure under extreme or unusual conditions must be performed. Some of these inspections may be performed on a sample basis. The reviewer must verify that the applicant has provided adequate information concerning the QC program.

Current practice allows acceptance of the submission of a QA program in lieu of a QC program. The QA program provides control over all activities applicable to the design, fabrication, inspection, testing, maintenance, repair, modification, and distribution of the sealed sources or devices. This puts more emphasis on the overall management structure and on the program that covers construction of the device from the time of initial design through refurbishment. Regulatory Guide 6.9, "Establishing Quality Assurance Programs for the Manufacture and Distribution of Sealed Sources and Devices Containing Byproduct Material," provides applicants with information necessary to establish and implement a QA program that encompasses all of the QA and QC requirements necessary for the manufacture and distribution of sealed sources and devices. The guide contains sample documentation and a checklist for assessing completeness and implementation of the program. QA programs submitted by applicants are evaluated against Regulatory Guide 6.9. It should be noted that Regulatory Guide 6.9 discusses acceptance of programs meeting the requirements of other established QA standards.

If the product is registered for use by a custom user, submission of a complete QC program may not be required. This is typical in a situation where only a limited number of units will be manufactured, usually one or two. Since the purpose of a QC program is to ensure all devices are manufactured to the same specifications, development and submission of a complete program may not be feasible. Since only one licensee is using the product, additional administrative controls can be implemented by the licensee.

The following regulations should be referenced for additional information concerning quality assurance and control:

Regulations	Applicability
10 CFR 32.55 & 32.110	Devices used under the 10 CFR 31.7 general license.
10 CFR 32.61(e)(5), 32.62, & 32.110	Devices used under the 10 CFR 31.10 general license.

10.8 Installation, Servicing, and Instructions to Users

The applicant should provide any special procedures that need to be followed when the product is installed at the user's facility. These include mounting, installing interlocks, guards or barriers, and determining whether the installation needs to be performed by a specific licensee. General licensees may be permitted to mount products, depending on their design.

An applicant may request that general and specific licensees, without specific authorization under that license, be permitted to mount products. In order for NRC to grant such a request, the applicant must provide justification for approval (e.g., likely doses to persons mounting the device, why specific training is not necessary to perform mounting) and must provide written procedures that must be followed to mount the product safely. The reviewer must evaluate the adequacy of the procedures. These procedures must indicate the following:

- that the product must be mounted in a location compatible with the "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use" on the registration certificate;
- that the on-off mechanism (shutter) must be locked in the off position, if applicable, or that the source must be otherwise fully shielded.;
- that the product must be received in good condition (package is not damaged); and
- that the product must not require any modification to fit in the proposed location.

The "Limitations ;and/or Other Considerations of Use" section of the registration certificate must specifically state that general or specific licensees, without specific authorization under their license, may mount the product.

In addition, the applicant needs to indicate whether other services necessary to support safe use of the products need to be performed by a specific licensee or may be performed by a general licensee. These include calibration, relocation, leak test, routine maintenance, radiation surveys, necessary training for users, changing of sources, and final disposal of the byproduct material. The applicant needs to indicate whether the applicant, or the manufacturer or distributor, will provide the necessary services or identify an entity that will provide such services. If the applicant cannot identify an entity that will provide the necessary services, the registration certificate should include this in a reviewer note. However, if the device is to be possessed and used by a general licensee, and the applicant cannot identify an entity that will provide services that cannot be performed by the general-licensed users, the device should not be registered. Reviewers should recognize that vendors or service companies may discontinue providing services. The NRC is typically notified when a vendor decides to no longer provide services.

Registration certificate holders requesting to transfer a registration certificate to inactive status should identify whether they plan to continue to provide services for the registered products or whether they are aware of an entity that will provide services. See Section 13.3, "Transfers to Inactive Status."

The reviewer needs to verify that procedures for servicing the product are adequate, can be performed by the persons indicated by the applicant (e.g., by a general licensee), and do not interfere with, or compromise, the integrity of the product.

The reviewer must verify that the distributor provides the user of the product with the information necessary to safely operate and maintain the product. These include instructions for operation, maintenance, calibration, damage/failure, specific warnings, leak tests, and radiation surveys. The distributor should also provide information to the user concerning who may provide services for the product. For devices distributed to general licensees, the distributor needs to provide copies of regulations governing use and transportation of the product and a listing of regulatory authorities who license possession and use of the product.

To assist the reviewer in determining whether certain activities may be performed by general licensees, the applicant must provide an estimate of the dose to a worker for each activity to be performed.

The reviewer needs to verify that the documentation provided to users of the products does not misinterpret, misrepresent, or lead the user into violating any applicable regulations.

Figure 10.2 Installation and Servicing of Devices. *Applicants must specify the qualifications needed by individuals to perform installation and servicing of devices.*

The following regulations should be referenced for additional information concerning servicing:

Regulations	Applicability
10 CFR 32.51(b) & (c)	Devices used under the 10 CFR 31.5 general license

10.9 Final Evaluation and Concurrence

Once the reviewer has evaluated all necessary information and has determined that the product is acceptable for licensing purposes, the information will be passed to a second reviewer to perform an independent technical evaluation. The second reviewer must independently arrive at the same finding as the initial reviewer. Any discrepancies between reviewers must be resolved before the registration certificate can be issued. Once both reviewers concur in the findings in the document, they will sign the certificate.

Typically, the initial reviewer will generate a draft registration certificate for evaluation by the second reviewer. The second reviewer will evaluate both the application and the draft registration certificate to ensure accuracy and completeness.

11 Deficiencies in the Application

In the process of evaluating an application, a reviewer may determine that insufficient information has been submitted. If this is the case, the reviewer must contact the applicant to obtain the information. Depending on the type of information needed, the reviewer may obtain the information by sending a formal written request to the applicant, requesting a meeting with applicant, notifying the applicant of the need for information via telephone or electronic mail, or

obtaining the information directly from the applicant during a telephone conversation or via electronic mail.

Because of the need to complete the application reviews in a timely manner, the reviewer should do the following when addressing deficiencies in applications:

11.1 Sending Deficiency Letters to Applicants

Any significant or complex deficiencies in an application for an evaluation must be set forth in a formal deficiency letter to the applicant. The letter should request that the response be provided in duplicate. The letter to the applicant should request that the applicant respond within a specified number of days from the date of the deficiency letter. The number of days is typically 30 to 60 days but depends on the complexity of the information and the level of effort needed by the applicant to respond (e.g., extra time may be needed to perform prototype testing on a product). In addition, the letter should indicate that if a written response[(9)] to the deficiency letter is not received within the number of days specified in the letter, the reviewer will consider the application as "abandoned"[(10)] for failure to provide the requested information "without prejudice" to the resubmission of a complete application.

Prompt action (5 working days) should be taken to "void" the application after the application has been considered as "abandoned." The reviewer should notify the applicant, in writing, that the application has been considered abandoned and the reviewer will place the application in the "void file." Void files should be placed in DCD in the manner described in Section 9.3.

If a response to the deficiency letter is received after the application has been voided and the response is received not more than 1 year from the date of the letter, the application should be assigned a new tracking number and handled as a new application; however, no additional fee may be necessary if it is a continuation of the evaluation. Higher priority will not be assigned solely based on the fact the application is a resubmission.

11.2 Meetings with Applicants

NRC or applicants may request meetings to discuss sealed source and device applications. The meetings may be prior to submission of an application or to discuss items included in a deficiency letter. Meetings between NRC and applicants may be at an NRC office, or at the applicant's facility if it is determined that it would enhance NRC's understanding of the product.

11.3 Use of the Telephone or Electronic Mail to Obtain Additional Information

There is no prohibition on using the telephone or electronic mail for obtaining clarifying information from an applicant. These mechanisms may be used to notify an applicant of simple deficiencies, to accelerate the review process.

Use of the telephone or electronic mail for notifying an applicant of deficiencies must be limited to items that are simple and such that they can be specified simply. Simple items include a model number for a sealed source, need for a applicant commitment to perform a procedure, or clarification of a material type or a dimension.

If the deficiency is a clarification of information provided in the application, it may not be necessary to have the applicant respond in writing. This decision is left to the discretion of the reviewer. However, the applicant's response, either via telephone or electronic mail, must be documented and included as part of the application.

In all cases, the telephone conversation or electronic mail transmitting deficiencies to an applicant must be documented by the person initiating the telephone call. If the applicant does not respond within 15 calendar days, a confirmatory letter must be sent to the applicant. The confirmatory letter must clearly specify the deficiencies and be handled as a typical deficiency letter with the exception that it includes a statement that the information needs to be received within a specified time frame or the application will be voided.

11.4 Response Time Extensions

A request from an applicant for an extension of time to respond to any correspondence about its application may be granted if it is determined that there is good cause to grant an extension. The request may be in writing or via the telephone. Typically, the reviewer responds by telephone to notify the applicant that an extension has been granted. All requests for extensions must be approved by Management and must be documented in a conversation record.

12 Contents of the Certificate

Registration certificates are written in a standard format. This allows license reviewers and inspectors to quickly retrieve information necessary to perform a license review, perform a site inspection, or respond to incidents involving lost, damaged, and/or abandoned sealed sources or devices.

The registration certificate is a summary of the technical evaluation of the product. It contains summaries of the areas examined during the evaluation process. Appendix H includes standard formats for registration certificates for a sealed source, for a device, and for an exempt device. Further clarification of the information that is included in a registration certificate is listed below.

12.1 Header

The header includes the title of the document, the registration number, date of issuance, page numbering, and the sealed source or device type. If the certificate is amended or corrected, this is indicated in the title; the page number of each corrected page(s) needs to be listed or the header notes that the certificate is amended in its entirety. The registration number is assigned by the

reviewer, in accordance with the numbering procedures in Appendix I. The issue date is the date the certificate has received both reviewer and concurrence signatures.

12.2 First Page Information

The first page of each certificate includes the name and complete address of the manufacturer and distributor, the model number of the sealed source or device, the manufacturer or distributor and model number for the sealed source incorporated in the device, isotopes, maximum allowable activity levels, leak test frequency, principal uses (including code and description), and an indication of whether the registered product is designed for custom use. If registered for custom use, the name and address of the custom user is included. This information is entered into the NRC maintained computerized registry of sealed sources and devices.

The following subsections are included in the order listed below starting on the second page of the certificate.

12.3 Description

This section provides a narrative description of the construction of the product, safety features of the product, and ON/OFF and safety indicators. The description should include the materials of construction and fabrication techniques for critical safety components of the product. These typically include source encapsulation materials, source holder materials, shutter mechanisms, welding process, and device security features, such as tamper resistant fasteners, locks, etc. Overall dimensions of the sealed source and the device are also included.

Certificates for sealed sources include the chemical and physical forms of the source material. Certificates for devices describe how the sealed source is secured within the device and how the product is protected from its intended environment (e.g., hermetically sealed, fire-proof, corrosion-resistant, etc.).

12.4 Labeling

This section describes how the labeling requirements are fulfilled. It lists the information that can be found on the label, construction of the label, and how and where the labeling is attached to the product. Any exemptions from labeling requirements or omissions of information typically included on the labels will be noted.

12.5 Diagrams

This section lists the diagrams, drawings, sketches, or pictures of the product that are included in the certificate. These are typically included as attachments to the certificate and should include overall dimensions of the product, the location of the sealed source within the device, and the safety related features of the product. A person using the certificate, such as an inspector or license reviewer, should be able to identify a device given the diagrams and the description from

the certificate.

12.6 Conditions of Normal Use

This section lists the environmental conditions the product is intended to withstand. The normal intended uses of the product and any limitations that define these uses are included in this section. The working life is also included.

12.7 Prototype Testing

This section describes tests performed on prototypes of the product to demonstrate it will maintain its integrity. If the product was tested in accordance with an applicable industry or consensus standard, the corresponding classification, as defined by the standard, should be stated in this section. If the product was tested in accordance with an applicable regulation, this section specifies whether the product satisfactorily met the requirements of the regulation.

If, in lieu of prototype testing a product, an applicant submitted operational history of the product or a similar product or provided an engineering analysis that demonstrates that the product is adequately designed, this section will provide the details of the operational history or analysis and the basis for determining the design to be adequate.

12.8 External Radiation Levels

This section states the maximum radiation levels from the product when loaded with the maximum activity of each nuclide or combination of nuclides. If the manufacturer is unable to provide measured external radiation levels for the product, a conservatively calculated maximum radiation profile is listed. If applicable, the radiation profiles are listed for shutter open and closed conditions. The stated levels are the maximum radiation levels expected from the product and take into consideration factors affecting the levels, such as whether product is present in the measuring area or whether certain areas around the device are restricted from access. Any significant contaminants that would change the expected radiation levels are stated. Ideally, the radiation levels listed in this section will include the levels on contact with the product, at 5, 30, and 100 cm (2.0, 11.8, and 39.4 in.) from the product, and in the beam.

Should there be a device containing a number of isotopes and designed with a range of dimensions, a distributor may commit to ensuring that the radiation levels do not exceed a specified level. If this is the situation, the certificate needs to include the maximum allowable radiation level and include limitations concerning the installation of the device.

12.9 Quality Assurance and Control

This section includes a summary of the QC procedures that will be followed to ensure the product meets all applicable specifications. If the QC procedures meet a national or industry

standard or regulation, it is specified in this section. In lieu of submitting QC procedures, an applicant may commit to following a QA program. Again, if the QA program meets a national or industry standard or regulation, it is specified in this section. If the applicant commits to following a complete QC or QA program, a short summary of the program may be included and this section should reference that details of the complete program are on file with the NRC. The section also contains a statement reflecting that the QC or QA program has been assessed and deemed acceptable by the NRC.

12.10 Limitations and other Consideration of Use

This section establishes the limiting conditions imposed on the sealed source or device. These include leak testing, handling, storage, use, transfer, disposal, environmental conditions, labeling, special handling procedures and tools, and specific licensing conditions that should be addressed by the license reviewer. This section needs to clearly indicate the services that may be performed by general-licensed users of the products, state that sources or devices should not be subjected to environments that exceed their ANSI or ISO classifications, and state that if subjected to such environments, the licensee must discontinue use of the source or device until a demonstration that no affect to the source or device integrity has occurred as a result of operation outside the specified range. It also includes a limitation that states that the registration certificate and the information contained within the references shall not be changed without the written authorization of the NRC.

Limitations on sealed sources and devices can be divided into two categories, the first being limitations placed on the manufacturer or distributor of the sealed source or device and the second being limitations placed on the user of the sealed source or device. Limitations of the first category are derived from regulations. In addition to regulations, the second category of limitations is also derived from conditions imposed by the manufacturer, by particular conditions of use that would reduce the radiation safety of the device, and by circumstances unique to the sealed source or device, which require that the sealed source or device receive a special limitation.

In addition, this section of the certificate may contain reviewer notes. The purpose of such notes is to identify to license reviewers areas of use of the product that cannot be controlled as part of the registration. This alerts the license reviewer to verify that the licensee implements certain administrative procedures before initial use, as part of routine use, or as part of an emergency response to an incident. For example, indicating in a reviewer note that a vendor no longer offers servicing for the product alerts the license reviewer to obtain more than a statement that services will be provided by the vendor.

12.11 Safety Analysis Summary

This section summarizes the conclusion of the evaluation performed by the reviewer and states that the product is acceptable for certain licensing conditions. Also, typically listed in this section are any additional features that the device, surroundings, environment, or accessories may

contribute to the integrity or safety of the product. These may include physical constraints such as barriers, fences, or guards and actual use time in terms of radiation exposure resulting from working around the product.

12.12 References

This section incorporates by reference the documents that were submitted in support of the application. These references include applications, letters, faxes, electronic mail messages, and enclosures to such documents. The applicant is required to adhere to the information and commitments included in these references.

12.13 Issuing Agency

This section identifies the NRC as the regulatory agency that issued the certificate and includes the date issued and the typed names and signatures of the two persons who reviewed the certificate and all applicable documentation. All certificates include two signatures as part of the quality control measures.

12.14 Attachments

This section typically contains diagrams, drawings, sketches, or pictures of the product, as discussed previously in Section 12.5. These provide inspectors a tool by which they can easily identify the devices in the field. The attachments also may contain designations of specific models and their characteristics, such as dimensions and sealed source activities, if a series of devices are registered.

The header for the attachments is similar to that for the main body of the registration certificate. The header contains the title of the document, registration number, date of issuance, and attachment numbering. The header does not contain the sealed source or device type.

12.15 Dimensions and use of Dual Units

The NRC's Metrication Policy (57 FR 46202) requires that documents specific to a registration certificate holder, such as the registration certificate, include dimensions in the units employed by the registration certificate holder. In addition to including the units employed by the registration certificate holder, it is recommended that registration certificates include dual-units as specified below:

- All measurements should be stated in the units employed by the registration certificate holder, followed by the appropriate English or International System of Units conversion in parentheses.

- All measurements not provided by the applicant should be specified in English units,

followed by the converted International System of Units value.

•The method of stating measurements for a specified property should be consistent throughout the document. If the measurement of the property is first stated in International System of Units, with the English conversion in parentheses, then all other measurements should be stated in International System of Units, with the English conversion in parentheses.

•If a value is being restated (i.e., the measurement is included in a table, was already stated in the same section of the document, or was included on the first page of the document (such as the maximum activity)), the restated measurement need not have the conversion following it since the conversion has already been included in the document.

13 Modifications to Existing Registration Certificates

It is the obligation of the registration certificate holder to keep the registration certificate current. If a registration certificate holder plans to make a change to the registered product that affects the commitments made in the information provided in support of the application or the conditions included in the registration certificate, the registration certificate holder must file for an amendment or correction to the registration certificate. Until the amendment request is approved and the amended certificate is issued, the registration certificate holder is obliged to comply with the information in the certificate. Registration certificate holders are encouraged to anticipate the need for certificate amendments as far in advance as possible.

An application to amend a certificate should be prepared in triplicate. The registration certificate holder should retain one copy for their records and submit the original and one additional copy to the address specified in Section 7. The application should identify the registration certificate by number and should clearly describe the changes and the effects of the changes on the safety properties of the product. References to previously submitted information should be clear and specific and should identify that information by date, document title, and page number.

An application to amend a certificate should be accompanied by the appropriate fee (Section 8) and, for medical products, the registration certificate holder needs to notify FDA about the proposed changes to the product.

The request for an amendment or correction needs to address the changes to the product and how the changes affect the original safety evaluation of the product. The reviewer needs to evaluate the changes to determine if they have any adverse effects on the safety of the product and whether the initial evaluation and the determination of adequacy are still valid. The reviewer needs to look at all aspects of the initial evaluation to determine if the change would have an effect on another aspect of the evaluation that may not be readily evident. For example, changing a part of the source holder from stainless steel to lead may improve the shielding efficiency, but may have detrimental effects on how the device will react to accident conditions. This type of detrimental effect may have been overlooked by the manufacturer.

13.1 Amendments

If the registration certificate holder requests an amendment to the certificate (i.e., it requires a safety evaluation to be performed), the certificate should be amended in its entirety. The certificate header should include, under the title, the following:

(AMENDED IN ITS ENTIRETY)

The certificate should be assigned a new issue date, and the certificate should be re-issued in its entirety. When appropriate, the reviewer should use bold type face and strike-out to highlight the changes that have been made to the certificate. In addition, if there are still products in use that meet the previous design specifications, reviewers must ensure that previous design information remains in the registration certificate. The registration certificate also must identify, by date or serial number, when the design change is implemented.

13.2 Corrections

If the change only involves corrections to the certificate (i.e, does not require a safety evaluation to be performed such as change in address or error identified in the certificate), then only the affected pages of the certificate need to be updated and issued. The reviewer should use bold type face to make the corrections. Each affected page should include, in the header, under the title, the words "CORRECTED PAGES," the number of each page affected, and the date of the correction. An example of this format is shown below:

(CORRECTED PAGES 1, 2, & 4 - JULY 5, 1776)

The issue date of the certificate should remain the same as the last issue date. It is not necessary to include the letter from the registration certificate holder in the reference section of the certificate.

If the correction requires a change to the signature page of the certificate, the certificate should be amended in its entirety. The reviewer may elect to hold off making corrections to the signature page until the registration certificate holder requests an amendment, requiring a safety evaluation, to the certificate.

13.3 Combining Registration Certificates

Registration certificate holders may request that NRC combine two or more certificates into a single certificate. However, it is IMNS policy that only products which are essentially identical in design, function, construction, and which vary only in a dimensional capacity, in the sources used or in their application, may be grouped together on a single registration certificate.

Combining registration certificates does not require a safety evaluation. However, the reviewer must determine whether the request meets IMNS policy and can administratively combine the

registration certificates.

13.4 Transfers to Inactive Status

If a registration certificate holder requests that a registration certificate be transferred to inactive status[(11)], the registration certificate holder should provide:

- the total number of the products sold; the number of products still in use[(12)];
- the services (including source replacement and availability) the registration certificate holder will still provide to users of the product or the identification of an entity that will provide services;
- a commitment that the registration certificate holder will no longer commercially distribute the product; and,
- verification that no changes were made to the product since its initial registration or last amendment.

The reviewer must verify that the above information is included and that the background file for the product evaluation is complete and accurate. Because some registrations were issued many years ago, the files may not include all the information that is now required. Therefore, the reviewer should request that the registration certificate holder submit any and all additional information that would be needed to make a determination that the product is acceptable for licensing purposes. The reviewer needs to write an updated registration certificate, including the new registration number (see Appendix J for issuance of inactive registration certificate numbers) and updated information. The new certificate will contain a statement that the product will no longer be commercially distributed but may still be approved for licensing purposes. The registration certificate will replace the old registration certificate and will be used as the basis for continued licensing of the product.

13.5 Re-activating Inactive Registration Certificates

Vendors may submit requests to re-activate inactive registration certificates. Requests to re-activate inactive registration certificates are handled in one of the two methods:

	1.	If the background information on file with the NRC for the inactive registration certificate is complete, up-to-date, and the vendor does not request any changes to the information, the vendor may simply submit a letter to the NRC requesting re-activation of the registration certificate. The letter must include commitments that the information on file with the NRC is complete and accurate and that the vendor commits to abide by all information on file with the NRC. The reviewer must verify the information is complete prior to assigning a new registration certificate number and re-issuing the certificate
	2.	If the background information on file with the NRC for the inactive registration certificate is incomplete, not up-to-date, or the vendor requests changes to the information (e.g., changes in the design of the product or manufacturing or distribution procedures), the vendor must submit a complete application for evaluation and registration in accordance with this document. The reviewer must review and evaluate the application in the same manner as a new application.

14 Identifying and Reporting Defects and Noncompliance as Required by 10 CFR Part 21

Registration certificate holders are required to adopt appropriate procedures to evaluate deviations in product designs or failures to comply with registration requirements to identify defects or failures to comply that are associated with a substantial safety hazard. A substantial safety hazard is defined in Part 21 as a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed, other than for export, pursuant to parts 30, 40, 50, 60, 61, 70, 71, or 72. However, NRC Information Notice 91-39: "Compliance with 10 CFR Part 21, Reporting of Defects and Noncompliance" (available from the NRC upon request) indicates that from a radiological perspective, a substantial radiation safety hazard exists if there is a potential for a moderate exposure to, or release of, licensed material. Further, it provides the following for determining moderate exposure or release of licensed material:

- Guidelines for determining moderate exposure:
    - Greater than 250 mSv (25 rem) exposure (whole body or its equivalent to other body parts) to occupationally exposed workers in a period of a year or less.
    - Greater than 5 mSv (0.5 rem) exposure (whole body or its equivalent to other body parts) to an individual in an unrestricted area in a period of a year or less.
- Guidelines for determining potential for release of licensed material:
    - Release of materials in amounts reportable under the provisions of 10 FR 20.2202(b)(2).

All defects or failures to comply that are associated with, or could lead to, a substantial safety hazard must be reported to the NRC pursuant to 10 CFR 21.21. In addition, registration certificate holders are required to meet the posting requirements specified in 10 CFR 21.6.

Applicants are not required to submit copies of the procedures that are necessary to meet the requirements of 10 CFR Part 21. However, applicants need to be aware of the need for such procedures and the NRC will evaluate the procedures during inspections.

15 Glossary

Active Registration Certificate means a registration certificate for a sealed source or device that may be authorized for initial distribution. It constitutes part of the basis for the NRC and Agreement States to issue licenses.

Active Vendor means a vendor, listed on a registration certificate, that may be authorized to initially distribute the sealed source or device listed on the registration certificate.

Agreement State means a State that has entered into an agreement with the NRC allowing the State to regulate the use of byproduct material within the State. A complete listing of the current Agreement States, including addresses and points of contacts, can be obtained from OSP.

Agreement State Registration Certificate means a registration certificate, issued and maintained by an Agreement State, for a sealed source or device evaluated by the Agreement State.

Applicant means a vendor or custom user of a product that applies for a certificate of registration with the NRC or an Agreement State. The applicant is responsible for ensuring the information provided in the application is complete and accurate.

Associated Equipment is equipment that is used in conjunction with a device and directly effects the safe use of the device or ensures the device maintains its integrity (e.g., parts that move a source, control the shielding of a source, control the radiation levels around a device, come in contact with the source). Associated equipment supplied by the vendor of the device should be evaluated and registered as part of a device. If the associated equipment is supplied by another vendor, the evaluation and registration should be handled the same as a device evaluation and a separate registration certificate should be issued for the equipment.

Custom User means a licensee that uses a product that is manufactured in accordance with the unique specifications of, and for use by, a single applicant. Typically, no more than two different NRC or Agreement State licensees may be custom users of, and may register, the same product. However, a custom user may acquire and/or use more than one product.

Inactive Registration Certificate means a registration certificate for a sealed source or device that may have been authorized for distribution at one time but no longer may be authorized for initial distribution. Unless otherwise stated in the registration certificate, the sealed source or device included on an inactive registration certificate still may be authorized for use and may continue to be licensed. The vendor listed on the registration certificate may be authorized to provide service and replacement parts for the sealed source or device and may be authorized to receive the sealed source or device from a user for disposal or redistribution to a licensee. However, the design of the sealed source or device cannot be changed.

The NRC and the Agreement States may continue to issue licenses to persons to use sealed sources or devices that are included on an inactive registration certificate. This typically would occur during renewal of a license. However, the fact that the registration certificate is inactive serves to alert the license reviewer that the user may not be able to find a firm to service the device or may not be able to find replacement parts. The license reviewer must ensure that emergency procedures, operational support, and services are still applicable.

Inactive Vendor means a vendor who no longer may be authorized to initially distribute the sealed source or device listed on a registration certificate but may be authorized to provide services for the sealed source or device.

Mounting means physically positioning the product into its permanent location, including

installation of fasteners (e.g., mounting bolts). Mounting does not include electrical connection, activation, or operation of the product.

NARM stands for Naturally occurring or Accelerator-produced Radioactive Material. This material is not subject to regulation by the NRC but is regulated by the States. FDA Center for Devices and Radiological Health assists States in their review and regulatory approval for distribution of devices containing NARM.

Product means any sealed source, device, or associated equipment registered with the NRC or an Agreement State.

Registration Certificate Holder means a vendor or custom user of a product that holds a certificate of registration with the NRC or an Agreement State. The registration certificate holder is responsible for ensuring the information in the registration certificate is current and correct and for ensuring products manufactured or distributed conform with the conditions of the certificate.

Vendor means any person, licensed or unlicensed, who manufactures or distributes products.

Working Life means the time period when the product is expected to maintain its integrity. The working life should is based on the radiotoxicity, total activity, product construction, normal operating environments, likely abnormal conditions, fatigue, and wear.

Appendix A: List of Approved Well-Logging Sources

List of Approved Well-Logging Sources

Date	From	To	Page	GIF (viewing)	TIFF (download for printing)
September 03, 1993	Carl J. Paperiello	Stuart A. Treby	1	srp00101.gif	srp00101.tif
			2	srp00201.gif	srp00201.tif
			3	srp00301.gif	srp00301.tif
			4	srp00401.gif	srp00401.tif
December 23, 1993	Stuart A. Treby	Carl J. Paperiello	1	srp00501.gif	srp00501.tif
			2	srp00601.gif	srp00601.tif
			3	srp00701.gif	srp00701.tif

Appendix B: Checklist for Requests to Withhold Information from Public Disclosure

Checklist for Requests to Withhold Information from Public Disclosure

In order to request that the NRC withhold information contained in an application from public disclosure, the applicant must submit the information and application, including an affidavit, in accordance with 10 CFR 2.790. The applicant should submit all of the following:	
[ ]	A proprietary copy of the information. Brackets should be placed around the material considered to be proprietary. This copy should be marked as proprietary.
[ ]	A non-proprietary copy of the information. Applicants should white out or black out the proprietary portions (i.e., those in the brackets), leaving the non-proprietary portions intact. This copy should **not** be marked as proprietary.
[ ]	An affidavit that:
[ ]	Is notarized.
[ ]	Clearly identifies (such as by name or title and date) the document to be withheld.
[ ]	Clearly identifies the position of the person executing the affidavit. This person must be an officer or upper-level management official who has been delegated the function of reviewing the information sought to be withheld and authorized to apply for withholding on behalf of the company.
[ ]	States that the company submitting the information is the owner of the information or is required, by agreement with the owner of the information, to treat the information as proprietary.
[ ]	Provides a rational basis for holding the information in confidence.
[ ]	Fully addresses the following issues:
[ ]	Is the information submitted to, and received by, the NRC in confidence? Provide details.

[ ]	To the best of applicant's knowledge, is the information currently available in public sources?
[ ]	Does the applicant customarily treat this information, or this type of information, as confidential? Explain why.
[ ]	Would public disclosure of the information be likely to cause substantial harm to the competitive position of the applicant: If so, explain why in detail. The explanation should include the value of the information to your company, amount of effort or money expended in developing the information, and the ease or difficulty of others to acquire the information.

Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned to inspect the documents. If the need arises, the NRC may send copies of this information to NRC consultants working in that area. The NRC will ensure that the consultants have signed the appropriate agreements for handling proprietary information.

If the basis for withholding this information from public inspection should change in the future such that the information could then be made available for public inspection, the applicant should promptly notify the NRC. The applicant also should understand that the NRC may have cause to review this determination in the future, for example, if the scope of a Freedom of Information Act request includes the information in question. In all review situations, if the NRC makes a determination adverse to the above, the applicant will be notified in advance of any public disclosure.

Appendix C: Application and Review Checklist

Application and Review Checklist

The Application and Review Checklist are shown on the following pages.

SUMMARY DATA	
Name and Complete Mailing Address of the Applicant:	**Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC:**

<table>
<tr><td colspan="2">The Applicant is (check one):</td><td colspan="2" rowspan="5">If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer:</td></tr>
<tr><td></td><td>Custom User</td></tr>
<tr><td></td><td>Manufacturer</td></tr>
<tr><td></td><td>Distributor</td></tr>
<tr><td></td><td>Manufacturer and Distributor</td></tr>
<tr><td colspan="2">If the Applicant Is a Custom User, Provide the Name and Complete Mailing Address of the Distributor:</td><td colspan="2">Provide the Name, Complete Mailing Address, and Function of Other Companies Involved:</td></tr>
<tr><td colspan="2">Model Number:</td><td colspan="2">Principal Use Code (see Appendix F):</td></tr>
<tr><td colspan="2" rowspan="5">Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.):</td><td colspan="2">For Use by:</td></tr>
<tr><td></td><td>Specific Licensees Only</td></tr>
<tr><td></td><td>General Licensees Only</td></tr>
<tr><td></td><td>Both Specific and General Licensees</td></tr>
<tr><td></td><td>Persons Exempt from Licensing</td></tr>
<tr><td colspan="2">Leak-Test Frequency:</td><td colspan="2" rowspan="2">Principal Section of the 10 CFR that Applies to the User (e.g., General Licensees under 10 CFR 31.5):</td></tr>
<tr><td></td><td>Periodic Leak-Testing is Not Required</td></tr>
<tr><td></td><td>6 Months</td><td colspan="2" rowspan="2">Radionuclides and Maximum Activities (including loading tolerance):</td></tr>
<tr><td></td><td>Attached is justification for a leak test frequency of greater than 6 months</td></tr>
</table>

CERTIFICATION:

THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30 AND 32 AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

Certifying Officer — Typed Name and Title

Signature: **Date:**

CHECKLIST		
Registration Certificate Holder:		
Model:		
DESCRIPTION	**OK/DEF**	**COMMENTS**
DESCRIPTION/CONSTRUCTION		
If registration certificate holder is requesting to register more than one source/device on a certificate, are designs similar enough to do so?		
Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)		
Assembly methods (screw, welds, etc.); verify integrity		
Source mounting (size and integrity) and security		